

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit	: 3739	Customer No.:	035811
Examiner	:		
Serial No.	: 10/589,182		
Filed	: August 11, 2006		
PCT No.	: PCT/FR2005/000338		
PCT Filed	: February 11, 2005		
Inventors	: Maurice Bourlion	Docket No.:	BDM-06-1208
	: Dominique Petit		
	: Gérard Vanacker	Confirmation No.:	5880
Title	: EXPLORATION DEVICE TO		
	: MONITOR THE PENETRATION		
	: OF AN INSTRUMENT IN AN		
	: ANATOMIC STRUCTURE		

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Dated: October 11, 2007

**PETITION UNDER 37 C.F.R. §1.47(a)**

**Mail Stop PCT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

Sir:

This is a petition to accept the attached Combined Declaration, Power of Attorney and Petition unsigned by the third listed inventor of record. Inventor Gérard Vanacker received multiple requests for his signature sent to his representative at Cabinet Versini-Campinchi & Associés, but has not returned the executed document. Joint inventors Maurice Bourlion and Dominique Petit hereby request that the Application be accepted and prosecuted on behalf of Mr. Vanacker.

**Statement of Facts**

Mr. Vanacker was employed by Spinevision on July 22, 1999 as shown in the Employment Contract in the attached Exhibit A. (An English translation of the Employment Contract is provided.) Mr. Vanacker is no longer employed by Spinevision. Mr. Vanacker was obligated to assign inventions to Spinevision as shown in the Employment Contract (see Article 13).

On October 26, 2006, Proskauer Rose LLP, Spinevision's representative, sent a letter to Mr. Vanacker's consultant Cabinet Versini-Campinchi & Associés with an Oath and an Assignment requesting Mr. Vanacker's signature. Neither Cabinet Versini-Campinchi & Associés nor Mr. Vanacker responded. Copies of the letter, an English translation of the letter, enclosures concerning the first listed invention, and proof of receipt by Cabinet Versini-Campinchi & Associés of the October 26, 2006 letter are attached as Exhibit B.

Proskauer Rose, on November 28, 2006, sent a follow-up letter with another Oath and Assignment to Cabinet Versini-Campinchi & Associés and requested that Mr. Vanacker execute the documents and return them to Proskauer Rose. Again, neither Mr. Vanacker nor Cabinet Versini-Campinchi & Associés replied. Copies of the letter, an English translation of the letter, enclosures concerning item 1 in the letter, and proof of receipt are submitted herewith as Exhibit C.

Lovells LLP, on September 19, 2007, sent a follow-up letter with another Oath and Assignment to Mr. Vanacker requesting that he execute the documents and return them to Lovells LLP. Again, Mr. Vanacker did not reply. Copies of the letter, an English of the letter and the enclosures referred to in the letter are submitted herewith as Exhibit D.

It is therefore believed that Mr. Vanacker has refused to sign the Declaration.

**Last Known Contact Information of Non-signing Inventor**

The last known address of Mr. Vanacker is:

Villa Saint Antoine  
2 rue du Sautiquet  
83380 Les Issambres

The last known address of Mr. Vanacker's representative is:

Cabinet Versini-Campinchi & Associés  
Monsieur Alexandre Merveille  
Avocat à la Cour  
4, rue de la Tour des Dames  
75009 Paris, France

The Combined Declaration, Power of Attorney and Petition executed by the other inventors is attached hereto.

The Commissioner is authorized to charge the late declaration fee (\$130) and the petition fee (\$200) to Deposit Account No. 50-2719.

Confirmation of the granting of this Petition is respectfully requested.

Respectfully submitted,



T. Daniel Christenbury  
Reg. No. 31,750  
Attorney for Applicants

TDC/sh  
(215) 656-3381

# **EXHIBIT A**



## **Employment Contract**

### **BETWEEN:**

SPINEVISION, a public company with 38,325 euros in capital, having corporate headquarters located on 22 rue Alphonse De Neuville, 75017 Paris, registered with the Registry of Commerce and Companies of Paris under the number 423 661 693 (hereafter "the Company"), and represented by Mrs. Sarah Sorrel-Dejerine in her capacity as President of the Board of Directors;

### **ON THE ONE HAND,**

And

Mr. Gérard VANACKER, a French citizen, domiciled at 52, avenue François Adam, 94100 ST MAUR;

### **ON THE OTHER HAND,**

### **THE PARTIES AGREE TO THE FOLLOWING:**

The Company has offered Gérard Vanacker, who has accepted, a position of employment under the following specific terms and conditions, as well as under conditions provided for by the National Collective Bargaining Agreement of Engineers and Metallurgy Executives (hereafter "Collective Bargaining Agreement"), and which is contingent on the results from the pre-employment medical examination.

#### **Article 1 – Functions – Promotions**

Gérard Vanacker begins service with the Company as the Director of Sales and Marketing, executive status, grade 240. Within the context of this position, Gérard Vanacker will be responsible for following the instructions that the Company will be giving him and will be responsible for reporting to the President of the Company as to the execution of his mission.

It is understood, and accepted by Gérard Vanacker that his position will be able to evolve and that the Company will be amenable to modifying and completing his functions and responsibilities.

#### **Article 2 – Place of Work**

The place of work is fixed at the headquarters of the Company and/or on the operational premises of the Company located in the Paris region, it being understood that the functions of Gérard Vanacker will result in frequent travel, within France and abroad.

#### **Article 3 – Freedom of Engagement**

Gérard Vanacker declares that he is not held to any other agreement with or obligation to any previous employers which would prevent him from working for the Company.

Gérard Vanacker declares that, during the entire duration of his employment with the Company, he will neither use nor divulge any confidential or secret processes information belonging to any of his previous employers.

#### **Article 4 – Duration**

The present contract is entered into for an indeterminate duration beginning from July 22, 1999.

#### **Article 5 – Obligations and Duties**

5.1 Gérard Vanacker is being hired to exercise his functions loyally and to the best of his abilities. He will not, except if he has received prior written authorization from the Company, be involved in any other professional activity of any type, nor will he involve himself in any manner with any activity that would be in competition with the Company or that is in conflict with the interests of the activities of the Company.

5.2 Within the context of his employment functions, Gérard Vanacker will be entitled to conclude any agreement which may undertake the Company in conformity with the policies and the directives passed by the board of directors of the Company.

5.3 All publications or communications of Gérard Vanacker concerning the activities or the interests of the Company will be preliminarily authorized by the President of the board of directors, except publications or communications concerning the promotion of sales of the Company or the daily functions of Gérard Vanacker.

#### **Article 6 – Compensation**

6.1 The Company will pay Gérard Vanacker a base annual gross salary of six hundred thousand (600,000) francs, payable in twelve monthly installments at the end of each month.

6.2 The Company will proceed annually with an evaluation of Gérard Vanacker's performance and will contemplate a procedure to increase his salary such that it is tied to his performance, at each anniversary date of the present contract. Despite all clauses contrary to the present contract, it is expressly agreed that all bonuses, incentives, commissions, gifts, or any other payment included in the compensation set forth in this Article 6 will not be considered an element of salary that Gérard Vanacker will have a contractual right to receive, but rather as generosity that the Company reserves the right to cease or revise at any moment and at its sole discretion.

(Please note that the original French version does not mention any article 6.3)

6.4 It has been agreed that the compensation of Gérard Vanacker will be based upon a 39-hour work week. However, it is understood that the said compensation will take into account the nature of the functions and responsibilities which have been entrusted to him and will remain independent of the time that he dedicates to accomplishing them, in the exercise of his functions.

#### **Article 7 – Vacation Pay**

Gérard Vanacker will benefit from vacation time set forth by law and the Collective Bargaining Agreement, of which the scheduling will be determined by agreement between the Company and Vanacker, taking into account the demands of his service.

#### **Article 8 – Incapacity**

In the event of incapacity to work following an illness or accident, Gérard Vanacker must inform the management from the beginning of the first workday of his incapacity by submitting a medical certificate to the personnel department of the Company. The Company reserves the right to submit Gérard Vanacker to an examination by a doctor of its choice.

#### **Article 9 – Expenses**

Within the context of the regulations/policies in place within the Company, Gérard Vanacker will be reimbursed, upon presentation of his justifications for incurring such expenses, for all his professional expenses, including his travel costs incurred within the context of his functions within the Company.

#### **Article 10 – Secret – Confidentiality**

10.1 Gérard Vanacker recognizes that the activities of the Company are based on specialized work and a specific know-how, and that confidential information will be communicated to him within the context of this present contract. The term "confidential information" means all information that is not known publicly, concerning the activities of the Company, including, without limitation, all plans, production procedures, product and formula specifications, methods, technical bulletins and product bulletins, all data regarding the equipment sold or data regarding performance of services, as well as studies, research and development programs, correspondences, client lists, names of clients or prospects, sales reports and financial information.

10.2 Gérard Vanacker agrees, for both during the time he is exercising his functions within the Company as well as after those responsibilities/functions end for whatever reason, to maintain in the strictest of confidences the Confidential Information and to neither use the information nor communicate it to any third parties, whether a human being or a corporation, without the preliminary, written consent of the Company.

#### **Article 11 – Non-Compete**

Gérard Vanacker is prohibited, during a period of one (1) year (renewable one time) from the end of his employment contract with the Company, for whatever the reason:

- (a) from leading directly or indirectly, alone or in concert, as head or agent of another corporation or person, any competitive activity against the Company, without the prior written consent of the Company. By using the term "lead", it includes all activity in which he would be engaged, have an interest or more generally be involved. The term "competing activity" refers to all activity in the domain of implants and spinal instruments.
- (b) In consideration for Gérard Vanacker's agreement not to compete, and pursuant to the provisions of the Collective Bargaining Agreement, Gérard Vanacker will receive, after the effective termination of his employment contract and during the entire duration of the non-compete prohibition, a monthly indemnity equal to five-tenths of the average monthly salary and advantages and contractual benefits of which Gérard Vanacker had benefited during the course of his last twelve months of employment with the Company.
- (c) The Company may however renounce its right to enforce the non-compete in any way—and, likewise, renounce its obligation of payment of the indemnity in consideration of that non-compete obligation—provided that it notifies Gérard Vanacker of its decision by letter with return receipt requested within 8 days following the notification of termination of the employment contract.
- (d) In the event of the breach of this non-compete clause by Gérard Vanacker, the Company reserves the right to pursue damages for any prejudice actually suffered by the Company and to move to enjoin any competitive activity.

#### **Article 12 – Non-Solicitation – No poaching**

Notwithstanding all other stipulations in the present contract, Gérard Vanacker also agrees that during the two years immediately following the termination of the present contract he will not:

- (a) sell any products or services door-to-door that could be potentially competitive with the products of the Company, the clientele of the Company or its affiliates;
- (b) do business with the products or services of any person or corporation which would have been the client of the Company or of its affiliates during the two (2) years prior to the departure of Gérard Vanacker from the Company;
- (c) employ people who were employees of the Company in the year preceding the termination of the present contract, nor hire them through any other people, establishments, companies by which he [Gérard Vanacker] could be employed, or in which he has a direct or indirect interest, and agrees that he will not use his influence



over any person employed by the Company to suggest to that person or persuade him to leave his current post.

#### **Article 13 – Intellectual Property and/or Trade Secret Rights**

If, pursuant to the provisions of the Collective Bargaining Agreement, in the exercise of his functions, which include a creative mission—which has been taking into consideration in determining his compensation—Gérard Vanacker created an invention, patentable or not, created any drawings, models, methods, programs, formulas or processes in relation with the company's activities, projects or research of the Company and susceptible to being protected, the intellectual property or trade secret rights to that creation belongs to the Company in full.

However, if an invention created by Gérard Vanacker in the context of his functions provided the Company with an exceptional interest which was not commensurately compensated for in the inventor's salary, then after the issuance of the patent, a supplemental compensation that could take the form of a global bonus paid in once or several installments will be paid to the inventor.

However, if Gérard Vanacker conceived of an invention or a creation covered above without the support, help or aid of the Company, and did not use any activities, nor studies, nor research of the company, the rights of the resulting intellectual property or trade secret belong to Gérard Vanacker.

#### **Article 14 – Termination**

In the event of the termination or suspension of the present contract for any reason (resignation, termination, retirement, medical leave spanning over three calendar months, etc.), Gérard Vanacker will return to the Company, at the time of his departure from the Company and whatever the duration of the present contract, all documents, notes, reports, accounting reports, drawings, lists, credit cards and correspondences, including all copies, as well as all material, computer or electronic support, equipment and the Company car, which remain at all times the property of the Company.

#### **Article 15 – Applicable Law**

The present contract is governed by the laws of France.

In double copies, July 22, 1999, executed in Paris

SpineVision represented by  
Mrs. Sarah Sorrel-Dejerine  
In her capacity as President of the Board of Directors

\_\_\_\_\_  
Gérard VANACKER

\*The signatures must be preceded by the phrase "read and approved"; each page must be initialed by both parties.

## **CONTRAT DE TRAVAIL**

### **ENTRE LES SOUSSIGNES:**

**SPINEVISION**, société anonyme au capital de 38.325 Euros, dont le siège social est situé 22 rue Alphonse De Neuville, 75017 Paris, immatriculée auprès du Registre du Commerce et des Sociétés de Paris sous le numéro 423 661 693 (ci-après la "Société"), représentée par Madame Sarah Sorrel-Dejerine en sa qualité de Président du Conseil d'administration ;

### **D'UNE PART,**

**ET**

**Monsieur Gérard VANACKER**, de nationalité française, demeurant au 52, avenue François Adam, 94100 ST MAUR ;

### **D'AUTRE PART,**

### **IL A ETE CONVENU ET ARRETE CE QUI SUIT :**

La Société engage Gérard Vanacker, qui accepte, aux termes et aux conditions particulières suivants ainsi qu'aux conditions prévues par la Convention Collective Nationale des ingénieurs et cadres de la métallurgie (ci-après "la Convention Collective"), sous réserve du résultat de la visite médicale d'embauche.

#### **Article 1 - Fonctions - Clause de mobilité**

Gérard Vanacker entre au service de la Société en qualité de Directeur des Ventes et du Marketing, statut cadre, coefficient 240. Dans le cadre de ses fonctions, Gérard Vanacker sera chargé de suivre les instructions que la Société pourra lui donner et rendre périodiquement compte au Président de la Société de l'exécution de sa mission.

Il est entendu, et accepté par Gérard Vanacker, que le poste de Gérard Vanacker pourra évoluer et que la Société pourra être amenée à modifier et compléter ses fonctions et responsabilités.

## Article 2- Lieu du travail

Le lieu du travail est fixé au siège social de la Société et/ou dans les locaux opérationnels de la Société situés dans la région parisienne, étant convenu que les fonctions de Gérard Vanacker le conduiront à se déplacer fréquemment, en France et à l'étranger.

## Article 3 - Liberté d'engagement

Gérard Vanacker déclare qu'il n'est tenu par aucun engagement à l'égard de précédents employeurs, qui l'empêcherait de rejoindre la Société.

Gérard Vanacker déclare que, pendant toute la durée de son emploi au sein de la Société, il n'utilisera ni ne divulguera aucune information confidentielle ou secret de fabrique appartenant à l'un quelconque de ses précédents employeurs.

## Article 4 - Durée

Le présent contrat est conclu pour une durée indéterminée à compter du 22 juillet 1999.

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## Article 5 - Obligations de fidélité

5.1 Gérard Vanacker s'engage à exercer ses fonctions loyalement et au mieux de ses aptitudes. Il ne pourra, sauf s'il en reçoit l'autorisation écrite et préalable de la Société, avoir aucune autre activité professionnelle quelle qu'elle soit, ni s'intéresser de quelque manière que ce soit à aucune activité entrant en concurrence ou en conflit d'intérêts avec les activités de la Société.

5.2 Dans le cadre de ses fonctions salariées, Gérard Vanacker pourra conclure tout accord engageant la Société en conformité avec la politique et les directives arrêtées par le conseil d'administration de la Société.

5.3 Toute publication ou communication de Gérard Vanacker concernant les activités ou les intérêts de la Société devront être préalablement autorisés par le Président du Conseil d'administration, sauf publication ou communication concernant la promotion des ventes de la Société ou les fonctions habituelles de Gérard Vanacker.

## Article 6- Rémunération

6.1 La Société versera à Gérard Vanacker un salaire de base annuel brut de six cent mille (600.000) francs, payable en douze mensualités à terme échu.

85D-  
W-

6.2 La Société procédera annuellement à une évaluation des résultats de Gérard Vanacker et pourra envisager de procéder à des augmentations de salaire liées auxdits résultats, à chaque date anniversaire du présent contrat. Nonobstant toute disposition contraire du présent contrat, il est expressément convenu que tout bonus, prime, commission, libéralité ou autre paiement s'ajoutant aux rémunérations du présent Article 6 ne sera pas considéré comme un élément de salaire que Gérard Vanacker serait contractuellement en droit de recevoir, mais comme une libéralité que la Société se réserve le droit de cesser ou réviser à tout moment et à sa seule discrétion.

6.4 La rémunération de Gérard Vanacker a été convenue sur la base d'un horaire hebdomadaire de 39 heures. Toutefois, il est entendu que ladite rémunération tient compte de la nature des fonctions et responsabilités qui lui sont confiées et restera indépendante du temps qu'il consacrera de fait, à l'exercice de ses fonctions.

#### Article 7 - Congés payés

Gérard Vanacker bénéficiera des congés prévus par la loi et la Convention Collective, dont l'époque sera déterminée par accord entre la Société et Gérard Vanacker, compte tenu des nécessités du service.

#### Article 8 - Maladie

En cas d'incapacité de travail par suite de maladie ou d'accident, Gérard Vanacker doit avertir la Direction dès le début du premier jour ouvrable de son incapacité en remettant un certificat médical au service du personnel de la Société. La Société se réserve le droit de faire procéder à une contre-visite par un médecin de son choix.

#### Article 9 - Frais

Dans le respect des règles en vigueur au sein de la Société, Gérard Vanacker sera remboursé, sur présentation de justificatifs, de toutes ses dépenses professionnelles, y compris les frais de déplacement exposés dans le cadre de ses fonctions au sein de la Société.

#### Article 10- Secret - Confidentialité

10.1 Gérard Vanacker reconnaît que les activités de la Société sont basées sur un travail spécialisé et un savoir-faire spécifique, et que des informations confidentielles lui seront communiquées dans le cadre du présent contrat. Le terme «Informations Confidentielles» signifie toutes informations qui ne sont pas connues du public, concernant les activités de la Société, y compris, sans limitation, tous plans, procédés de production, spécifications de produits et formules, méthodes, bulletins techniques et bulletins produits, toutes données concernant les équipements vendus ou faisant l'objet de prestations de service, ainsi que les études, programmes de recherche et développement, correspondances, listes de clients, noms des clients ou prospectus, rapports de vente et informations financières.



10.2 Gérard Vanacker s'engage, tant pendant la durée de ses fonctions au sein de la Société qu'après leur cessation pour quelque raison que ce soit, à conserver la confidentialité la plus stricte sur les Informations Confidentielles et à ne pas les utiliser, ni les communiquer à un tiers, personne physique ou morale, sans l'accord préalable et écrit de la Société.

#### Article 11 - Non-concurrence

Gérard Vanacker s'interdit, pendant une période d'un (1) an (renouvelable une fois) à compter de la cessation de son contrat de travail au sein de la Société, pour quelque motif que ce soit:

- (a) à ne pas mener directement ou indirectement, seul ou de concert, comme dirigeant ou préposé de toute autre personne morale ou physique, une activité concurrente à celle de la Société, sans le consentement écrit et préalable de la Société. Par l'utilisation du terme "mener", on entend toute activité dans laquelle il serait engagé, intéressé ou plus généralement impliqué. Par "activité concurrente", il faut entendre, toute activité dans le domaine des implants et des instruments rachidiens.
- (b) En contrepartie de l'obligation de non-concurrence ci-dessus et conformément aux dispositions de la Convention Collective, Monsieur Gérard Vanacker percevra, après la cessation effective de son contrat de travail et pendant toute la durée de cette interdiction, une indemnité mensuelle égale à cinq dixièmes de la moyenne mensuelle des appointements et des avantages et gratifications contractuels dont Gérard Vanacker a bénéficié au cours de ses douze derniers mois de présence dans la Société.
- (c) La Société pourra cependant renoncer au bénéfice de l'obligation de non concurrence visée plus haut - et par là-même se dégager du paiement de l'indemnité prévue en contrepartie - sous réserve de notifier cette décision à Monsieur Gérard Vanacker par lettre recommandée avec accusé de réception dans les huit jours qui suivent la notification de la rupture du contrat de travail.
- (d) En cas de non-respect de la présente clause de non-concurrence par Monsieur Gérard Vanacker, la Société se réserve le droit de le poursuivre en remboursement du préjudice effectivement subi et de faire ordonner sous astreinte la cessation de l'activité concurrentielle.

#### Article 12 - Non-sollicitation - Non-débauchage

Nonobstant toute autre stipulation du présent contrat, Monsieur Gérard Vanacker s'engage par ailleurs pendant une durée de deux ans à compter de la résiliation du présent contrat :

- (a) à ne pas démarcher, pour tout produit ou service susceptible de faire concurrence aux produits de la Société, la clientèle de la Société ou de ses sociétés affiliées ;

- (b) à ne pas traiter pour ces produits ou services avec toute personne physique ou morale qui aura été le client de la Société ou de ses sociétés affiliées à quelque moment que ce soit pendant les deux (2) années précédant le départ effectif de Gérard Vanacker de la Société ;
- (c) à ne pas employer les personnes qui étaient employées par la Société dans l'année précédant la résiliation du présent contrat, ni les faire employer par toutes autres personnes, établissements, sociétés par lesquels il pourrait être employé, ou auxquels il pourrait être directement ou indirectement intéressé, et à ne pas utiliser son influence sur toute personne employée par la Société dans le but de lui suggérer ou de la persuader de quitter son poste.

### **Article 13 - Droits de propriété intellectuelle et/ou industrielle**

Si, conformément aux dispositions de la Convention Collective, dans l'exercice de ses fonctions, qui comportent une mission inventive -ce dont il a été tenu compte dans la détermination de sa rémunération- Gérard Vanacker réalisait une invention, brevetable ou non, créait des dessins, modèles, méthodes, programmes, formules ou procédés ayant trait aux activités, projets ou recherches de la Société et susceptibles d'être protégés, les droits de propriété intellectuelle ou industrielle appartiendraient à la Société de plein droit.

Toutefois, si une invention dont Gérard Vanacker serait l'auteur dans le cadre de ses fonctions présentait pour la Société un intérêt exceptionnel dont l'importance serait sans commune mesure avec le salaire de l'inventeur, celui-ci se verrait attribuer après la délivrance du brevet, une rémunération supplémentaire pouvant prendre la forme d'une prime globale versée en une ou plusieurs fois.

Toutefois, Si Gérard Vanacker réalisait une invention ou une création visée ci-dessus sans le concours de la Société, et n'ayant trait ni aux activités, ni aux études ou recherches de la Société, les droits de propriété intellectuelle ou industrielle en résultant appartiendraient à Gérard Vanacker.


### **Article 14 - Résiliation**

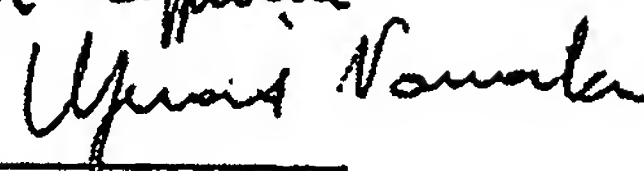
En cas de résiliation ou de suspension du présent contrat pour quelque raison que ce soit (démission, licenciement, départ en retraite, congé-maladie supérieur à trois mois civils, etc.), Gérard Vanacker remettra à la Société, lors de son départ de la Société et quelle que soit la durée du présent contrat, tous documents, notes, rapports, comptes-rendus, dessins, listes, cartes de crédit et correspondances, y compris toutes copies, ainsi que tout matériel, supports informatiques ou électroniques, équipement et véhicule de fonctions, qui demeureront à tout moment la propriété de la Société.

**Article 15 - Loi applicable**

Le présent contrat est soumis au droit français.

En double exemplaire, le 22 juillet 1999, à Paris

  
SpineVision représentée par  
Madame Sarah Sorrel-Dejerine  
en sa qualité de Président du Conseil d'administration ;

*lu et approuvé*  
  
Gérard VANACKER

- \* *Les signatures doivent être précédées de la mention manuscrite «Lu et approuvé» ;  
chaque page doit être paraphée par les deux parties.*

# **EXHIBIT B**

Paris, October 26, 2006

Cabinet Versini-Campinchi & Associés  
Monsieur Alexandre Merveille  
Avocat à la Cour  
4, rue de la Tour des Dames  
75009 Paris

By Courier

Official Letter

Re: Spinevision / Vanacker

Dear Colleague:

Enclosed are the documents (powers of attorney and transfer deed) which must be signed, notably, by your client, Mr. Gérard Vanacker, so that the following patents may be registered with the requisite authorities in the United States:

- Exploration device for monitoring the penetration of an instrument into an anatomical structure;
- Device for following the penetration of an instrument in an anatomical structure;
- Device for monitoring the penetration of an instrument into an anatomical structure;

Please return them to us as soon as possible.

In the event that your client does not agree to execute these documents, please notify us as soon as possible.

Please do not hesitate to let us know if you need any additional information.

Sincerely,

Yasmine Tarasewicz / Béatrice Pola  
Attorneys At Law

PJ.

C.C.: Société Spinevision

**PROSKAUER ROSE**

Avocats au Barreau de Paris

374, rue Saint-Honoré  
75001 Paris, France  
Téléphone 33.1.53.05.60.00  
Fax 33.1.53.05.60.05  
Palais J043

NEW YORK  
LOS ANGELES  
WASHINGTON  
BOCA RATON  
BOSTON  
NEWARK

Paris, le 26 octobre 2006

Cabinet Versini-Campinchi & Associés  
Monsieur Alexandre Merveille  
Avocat à la Cour  
4, rue de la Tour des Dames  
75009 Paris

Par porteur

Lettre officielle

Objet : Spinevison / Vanacker

Cher Confrère,

Vous trouverez ci-après les documents (pouvoirs et cessions) qui doivent être signés, notamment, par votre client, Monsieur Gérard Vanacker, afin que les brevets :

- Exploration device for monitoring the penetration of an instrument into an anatomical structure ;
- Device for following the penetration of an instrument in an anatomical structure ;
- Device for monitoring the penetration of an instrument into an anatomical structure ;

soient déposés devant les autorités requises aux Etats-Unis.


Nous vous remercions de bien vouloir nous retourner rapidement ces derniers.

Dans l'hypothèse où votre client n'entendrait pas procéder à ces signatures, nous vous remercions de bien vouloir nous le préciser en retour.

Nous restons bien entendu à votre entière disposition pour tout renseignement complémentaire que vous pourriez souhaiter.

Nous vous prions de nous croire, Cher Confrère,

Vos bien dévouées.



Yasmine Tarasewicz / Béatrice Pola  
Avocats à la Cour

PJ.

C.C. : Société Spinevision

- ☐ Original Application  
☒ PCT National Application  
U.S. Designated Office  
☐ Continuation or Divisional Application  
☐ Continuation-in-Part Application

**COMBINED DECLARATION,  
POWER OF ATTORNEY AND PETITION**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **EXPLORATION DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE**

☐ which is described in the specification and claims

☐ attached hereto.

☐ filed on \_\_\_\_\_

Application Serial No. \_\_\_\_\_

and was amended on \_\_\_\_\_  
(if applicable)

☒ which is described in International Application No. PCT/FR2005/000338 filed February 11, 2005 and as amended on \_\_\_\_\_  
(if any),

which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.



# COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION

(Page 2)

Attorney Docket No. BDM-06-1208

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International Application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application(s) for patent or inventor's certificate or of any PCT International Application having a filing date before that of the application on which priority is claimed:

Number	Country	Date of Filing (day,month,year)	Priority Claimed
FR 04/01361	France	11 February 2004	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
			<input type="checkbox"/> yes <input type="checkbox"/> no
			<input type="checkbox"/> yes <input type="checkbox"/> no
			<input type="checkbox"/> yes <input type="checkbox"/> no
			<input type="checkbox"/> yes <input type="checkbox"/> no

I hereby claim the benefit under Title 35, United States Code, §119(e) or §120 (as applicable) of any United States application(s) or §365(c) of any PCT International Application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International Application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112:

\_\_\_\_\_  
(Application Serial No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Status)(patented,pending,abandoned)

\_\_\_\_\_  
(Application Serial No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Status)(patented,pending,abandoned)

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following registered attorneys to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith:

T. Daniel Christenbury Reg. No. 31,750  
 Paul A. Taufer Reg. No. 35,703  
 Thomas J. Durling Reg. No. 31,349  
 Darius C. Gambino Reg. No. 41,472  
 William F. Lang Reg. No. 41,928  
 Paul Carango Reg. No. 42,386

Steven A. Nash Reg. No. 45,507  
 Andrew A. Noble Reg. No. 48,651  
 Thomas R. Mancini Reg. No. 50,157  
 Richard L. Cruz Reg. No. 52,783  
 William L. Bartow Reg. No. 54,981

**SEND CORRESPONDENCE TO:**  
 Customer No. 035811, whose contact information is:  
 IP Department of Piper Rudnick LLP  
 One Liberty Place, Suite 4900  
 1650 Market Street  
 Philadelphia, PA 19103

**DIRECT TELEPHONE CALLS TO  
 ATTORNEY OF RECORD AT:**

(215) 656-3300

# COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION

(Page 3)

Attorney Docket No. BDM-06-1208

I hereby petition for grant of a United States Letters Patent on this invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1. FULL NAME OF SOLE OR FIRST INVENTOR Maurice Bourlion		INVENTOR'S SIGNATURE		DATE
RESIDENCE Saint-Chamond, France		CITIZENSHIP France		
POST OFFICE ADDRESS 9, rue Jean Vincent, F-42400 Saint-Chamond, France				
2. FULL NAME OF JOINT INVENTOR, IF ANY Dominique Petit		INVENTOR'S SIGNATURE		DATE
RESIDENCE Verton, France		CITIZENSHIP France		
POST OFFICE ADDRESS 2, rue des Peupliers, F-62180 Verton, France				
3. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY Gérard Vanacker		INVENTOR'S SIGNATURE		DATE
RESIDENCE Tiburon, California, U.S.A.		CITIZENSHIP France		
POST OFFICE ADDRESS 4131 Paradise Drive, US-94920 Tiburon, California, U.S.A.				
4. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY		INVENTOR'S SIGNATURE		DATE
RESIDENCE		CITIZENSHIP		
POST OFFICE ADDRESS				
5. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY		INVENTOR'S SIGNATURE		DATE
RESIDENCE		CITIZENSHIP		
POST OFFICE ADDRESS				
6. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY		INVENTOR'S SIGNATURE		DATE
RESIDENCE		CITIZENSHIP		
POST OFFICE ADDRESS				
7. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY		INVENTOR'S SIGNATURE		DATE
RESIDENCE		CITIZENSHIP		
POST OFFICE ADDRESS				

sign here

ASSIGNMENT

WHEREAS, we, Maurice Bourlion, Dominique Petit and Gérard Vanacker, citizens of France, residing at 9, rue Jean Vincent, F-42400 Saint-Chamond, France, 2, rue des Peupliers, F-62180 Verton, France and 4131 Paradise Drive US-94920 Tiburon, California, U.S.A., respectively, (hereinafter referred to as "the undersigned"), having made an invention entitled EXPLORATION DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE, for which on the date set forth below, unless otherwise indicated here, \_\_\_\_\_, the undersigned executed an application for United States Letters Patent,

WHEREAS, Spinevision, a corporation of France, with offices at 180, avenue Daumesnil, F-75012 Paris, France (hereinafter referred to as "assignee"), is desirous of acquiring the entire right, title and interest in said invention, said application and all letters patent issuing for said invention,

NOW, THEREFORE, in consideration of One Dollar (\$1.00) and of other good and valuable consideration, receipt of which is hereby acknowledged, the undersigned, intending to be legally bound, does hereby sell, assign and transfer to the assignee the entire right, title and interest, for the United States of America, its territories and possessions, and for all foreign countries, in said invention, including said patent application, all divisions and continuations thereof, all rights to claim priority based thereon, all rights to file foreign applications on said invention, and all letters patent and reissues thereof, issuing for said invention in the United States of America and in any and all foreign countries.

It is agreed that the undersigned shall be legally bound, upon request of the assignee, or its successors or assigns or a legal representative thereof, to supply all information and evidence of which the undersigned has knowledge or possession, relating to the making and practice of said invention, to testify in any legal proceeding relating thereto, to execute all instruments proper to patent the invention in the United States of America and foreign countries in the name of the assignee, and to execute all instruments proper to carry out the intent of this instrument. If the undersigned includes more than one individual, these obligations shall apply to all of the undersigned both individually and collectively.

The rights and property herein conveyed by the undersigned are free and clear of any encumbrance.

EXECUTED on \_\_\_\_\_, 20\_\_\_\_, at \_\_\_\_\_.

\_\_\_\_\_  
Maurice Bourlion

\_\_\_\_\_  
Dominique Petit

\_\_\_\_\_  
Gérard Vanacker

\_\_\_\_\_  
Witness

sign here

66.500.001

N° 128293

Date : 26/10/06		Coursier : _____	<input type="checkbox"/> Normal	<input type="checkbox"/> Urgent	<input checked="" type="checkbox"/> Exclu
<b>EXPEDITEUR</b>			<b>CACHET OBLIGATOIRE :</b>		
NOM / SOCIETE : PROSKAUER ROSE LLP			PROSKAUER ROSE LLP		
ADRESSE : 374 rue Saint-Honoré 75001 Paris, France			374 rue Saint-Honoré 75001 Paris, France		
Tél : 01 53 05 60 00 - Fax : 01 53 05 60 05			Tél : 01 53 05 60 00 - Fax : 01 53 05 60 05		
Ville et code postal : 75001 Paris			Siret n° : 407 913 847 00031		
Demandeur : _____			Signature : _____		
<b>DESTINATAIRE</b>			<b>CACHET OBLIGATOIRE :</b>		
NOM / SOCIETE : Obriet Verbi			VERBI		
ADRESSE : 4 rue de la Tour des dames			Société d'Avocats au barreau de Paris 4, rue de la Tour des Dames 75009 PARIS Tél. 01 45 26 62 41 - Fax 01 48 78 26 52 Vern # 402		
Ville et code postal : 75009 PARIS			Heure de livraison : _____		
Réceptionnaire : Mr Meunier Alexandre			Signature : _____		
Facturer à : _____			Nombre de bons : 6		
Observations : Philia (B. Pda)					

# **EXHIBIT C**

Paris, November 28, 2006

Cabinet Versini-Campinchi & Associés  
Monsieur Alexandre Merveille  
Avocat à la Cour  
4, rue de la Tour des Dames  
75009 Paris

Registered Letter

Official Letter

Re: Spinevision / Vanacker

Dear Colleague:

We have sent you a letter on October 26, 2006, to which we have received no response.

We now ask that you convey to your client, Mr. Gérard Vanacker, the three powers of attorneys and the three transfer deeds pertaining to the three patents, all of which are documents he must sign.

Hereinafter is a new copy of the elements, as well as the complementary documents for each of the patents (a copy of the texts filed at the U.S. Patent Office at the national level for a request for a PCT (Patent Cooperation Traite) patent. Thus,

1. With regard to the patent for "Exploration device for monitoring the penetration of an instrument into an anatomical structure," the copies of the following are enclosed:
  - a. The power of attorney
  - b. The transfer deed
  - c. The French text for the international request for a PCT patent N°PCT/FR2005/000338;
  - d. The English text of the U.S. phase of the request for a PCT patent N°PCT/FR2005/000338;
  - e. The modified text of the request for a PCT patent pursuant to the requirements of the U.S. Patent Office (Clean Copy).
2. With regard to the patent for "Device for following the penetration of an instrument in an anatomical structure," copies of the following are enclosed:
  - a. The power of attorney
  - b. The transfer deed
  - c. The French text for the international request for a PCT patent N°PCT/FR2005/000873;
  - d. The English text of the U.S. phase of the request for a PCT patent N°PCT/FR2005/000873;



- e. The modified text of the request for a PCT patent pursuant to the requirements of the U.S. Patent Office (Clean Copy).
3. With regard to the patent for "Device for monitoring the penetration of an instrument into an anatomical structure," copies of the following are enclosed:
- a. The power of attorney
  - b. The transfer deed
  - c. The French text for the international request for a PCT patent N°PCT/FR2005/000340;
  - d. The English text of the U.S. phase of the request for a PCT patent N°PCT/FR2005/000340;
  - e. The modified text of the request for a PCT patent pursuant to the requirements of the U.S. Patent Office (Clean Copy).

Please inform us within a week as to the intentions of your client.

In the absence of a response, we will conclude that your client does not intend to associate himself with the three entry national phases in the United States for the PCT patents filed under the following numbers PCT/FR2005/000340, PCT/FR2005/000338 and PCT/FR2005/000873 before the U.S. Patent Office.

Sincerely,

Béatrice Pola  
Attorney At Law

PJ.

C.C.: Société Spinevision

2A 3261 9436 1FE

**PROSKAUER ROSE**

Avocats au Barreau de Paris

374, rue Saint-Honoré  
75001 Paris, France  
Téléphone 33.1.53.05.60.00  
Fax 33.1.53.05.60.05  
Palais J043

NEW YORK  
LOS ANGELES  
WASHINGTON  
BOCA RATON  
BOSTON  
NEWARK

Paris, le 28 novembre 2006

Cabinet Versini-Campinchi & Associés  
Monsieur Alexandre Merveille  
Avocat à la Cour  
4, rue de la Tour des Dames  
75009 Paris

**LETTRE RECOMMANDEE AR**

**Lettre officielle**

Objet : Spinevison / Vanacker

Cher Confrère,

Nous vous avons adressé le 26 octobre courant une correspondance qui, à ce jour, est restée sans réponse.

Dans cette dernière, nous vous demandions de bien vouloir transmettre à votre client, Monsieur Gérard Vanacker les trois pouvoirs et les trois cessions relatifs à trois brevets, documents qu'il devait signer.

Vous trouverez ci-après une nouvelle copie de ces éléments ainsi que pour chacun des brevets des documents complémentaires (copie des textes déposés à l'office américain des brevets pour la phase nationale de la demande de brevet PCT (Patent Cooperation Traite)). Ainsi,

1. S'agissant du brevet : *"Exploration device for monitoring the penetration of an instrument into anatomical structure"*, vous trouverez ci-après copies :

- du pouvoir,
- de l'acte de cession,
- du texte français de la demande internationale de brevet PCT  
N°PCT/FR2005/000338 ;
- du texte anglais de la phase nationale américaine de la demande de brevet  
PCT N°PCT/FR2005/000338 ;
- du texte modifié de la demande de brevet PCT qui répond aux exigences de  
l'office américain de dépôt des brevets (Clean Copy).



2. S'agissant du brevet : *"Device for following the penetration of an instrument in an anatomical structure"* vous trouverez ci-après copies :

- du pouvoir,
- de l'acte de cession,
- du texte français de la demande internationale de brevet PCT  
N°PCT/FR2005/000873 ;
- du texte anglais de la phase nationale américaine de la demande de brevet  
PCT N°PCT/FR2005/000873 ;
- du texte modifié de la demande de brevet PCT qui répond aux exigences de  
l'office américain de dépôt des brevets (Clean Copy).

3. S'agissant du brevet : *"Device for monitoring the penetration of an instrument into an anatomical structure"* vous trouverez ci-après copies :

- du pouvoir,
- de l'acte de cession,
- texte français de la demande internationale de brevet PCT  
N°PCT/FR2005/000340 ;
- texte anglais de la phase nationale américaine de la demande de brevet  
PCT N°PCT/FR2005/000340 ;
- texte modifié de la demande de brevet PCT qui répond aux exigences de  
l'office américain de dépôt des brevets (Clean Copy).

Je vous remercie de bien vouloir nous fixer sous huitaine sur les intentions de votre client.

A défaut de réponse, j'en conclurai que votre client n'entend pas s'associer aux trois entrées en phase nationale aux Etats-Unis des demandes de brevets PCT déposées sous les numéros PCT/FR2005/000340, PCT/FR2005/000338 et PCT/FR2005/000873 auprès de l'office américain des brevets.

Je vous prie de me croire, Cher Confrère,

Votre bien dévouée.

Béatrice Pola  
Avocat à la Cour

PJ.

C.C. : Société Spinevision

Groupement de droit étranger.  
Membre d'une association agréée. Le règlement des honoraires par chèque est accepté.

- ☐ Original Application  
☒ PCT National Application  
U.S. Designated Office  
☐ Continuation or Divisional Application  
☐ Continuation-in-Part Application

**COMBINED DECLARATION,  
POWER OF ATTORNEY AND PETITION**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **EXPLORATION DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE**

☐ which is described in the specification and claims.

☐ attached hereto.

☐ filed on \_\_\_\_\_

Application Serial No. \_\_\_\_\_

and was amended on \_\_\_\_\_  
(if applicable)

☒ which is described in International Application No. PCT/FR2005/000338 filed February 11, 2005 and as amended on \_\_\_\_\_  
(if any),

which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

# COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION

(Page 2)

Attorney Docket No. BDM-06-1208

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International Application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application(s) for patent or inventor's certificate or of any PCT International Application having a filing date before that of the application on which priority is claimed:

Number	Country	Date of Filing (day, month, year)	Priority Claimed
FR 04/01361	France	11 February 2004	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
			<input type="checkbox"/> yes <input type="checkbox"/> no
			<input type="checkbox"/> yes <input type="checkbox"/> no
			<input type="checkbox"/> yes <input type="checkbox"/> no
			<input type="checkbox"/> yes <input type="checkbox"/> no

I hereby claim the benefit under Title 35, United States Code, §119(e) or §120 (as applicable) of any United States application(s) or §365(c) of any PCT International Application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International Application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112:

(Application Serial No.)

(Filing Date)

(Status)(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)(patented, pending, abandoned)

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following registered attorneys to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith:

T. Daniel Christenbury Reg. No. 31,750  
 Paul A. Taufer Reg. No. 35,703  
 Thomas J. Durling Reg. No. 31,349  
 Darius C. Gambino Reg. No. 41,472  
 William F. Lang Reg. No. 41,928  
 Paul Carango Reg. No. 42,386

Steven A. Nash Reg. No. 45,507  
 Andrew A. Noble Reg. No. 48,651  
 Thomas R. Mancini Reg. No. 50,157  
 Richard L. Cruz Reg. No. 52,783  
 William L. Bartow Reg. No. 54,981

**SEND CORRESPONDENCE TO:**  
 Customer No. 035811, whose contact information is:  
 IP Department of Piper Rudnick LLP  
 One Liberty Place, Suite 4900  
 1650 Market Street  
 Philadelphia, PA 19103

**DIRECT TELEPHONE CALLS TO  
 ATTORNEY OF RECORD AT:**  
 (215) 656-3300

**COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION**  
(Page 3)

Attorney Docket No. BDM-06-1208

I hereby petition for grant of a United States Letters Patent on this invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that those statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1. FULL NAME OF SOLE OR FIRST INVENTOR <b>Maurice Bourlion</b>		INVENTOR'S SIGNATURE	DATE
RESIDENCE <b>Saint-Chamond, France</b>		CITIZENSHIP <b>France</b>	
POST OFFICE ADDRESS <b>9, rue Jean Vincent, F-42400 Saint-Chamond, France</b>			
2. FULL NAME OF JOINT INVENTOR, IF ANY <b>Dominique Petit</b>		INVENTOR'S SIGNATURE	DATE
RESIDENCE <b>Verton, France</b>		CITIZENSHIP <b>France</b>	
POST OFFICE ADDRESS <b>2, rue des Peupliers, F-62180 Verton, France</b>			
3. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY <b>G�rard Vanacker</b>		INVENTOR'S SIGNATURE	DATE
RESIDENCE <b>Tiburon, California, U.S.A</b>		CITIZENSHIP <b>France</b>	
POST OFFICE ADDRESS <b>4131 Paradise Drive, US-94920 Tiburon, California, U.S.A.</b>			
4. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
POST OFFICE ADDRESS			
5. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
POST OFFICE ADDRESS			
6. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
POST OFFICE ADDRESS			
7. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY		INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP	
POST OFFICE ADDRESS			

sign here

ASSIGNMENT

WHEREAS, we, Maurice Bourlion, Dominique Petit and Gérard Vanacker, citizens of France, residing at 9, rue Jean Vincent, F-42400 Saint-Chamond, France, 2, rue des Peupliers, F-62180 Verton, France and 4131 Paradise Drive US-94920 Tiburon, California, U.S.A., respectively, (hereinafter referred to as "the undersigned"), having made an invention entitled EXPLORATION DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE, for which on the date set forth below, unless otherwise indicated here, \_\_\_\_\_, the undersigned executed an application for United States Letters Patent,

WHEREAS, Spinevision, a corporation of France, with offices at 180, avenue Daumesnil, F-75012 Paris, France (hereinafter referred to as "assignee"), is desirous of acquiring the entire right, title and interest in said invention, said application and all letters patent issuing for said invention,

NOW, THEREFORE, in consideration of One Dollar (\$1.00) and of other good and valuable consideration, receipt of which is hereby acknowledged, the undersigned, intending to be legally bound, does hereby sell, assign and transfer to the assignee the entire right, title and interest, for the United States of America, its territories and possessions, and for all foreign countries, in said invention, including said patent application, all divisions and continuations thereof, all rights to claim priority based thereon, all rights to file foreign applications on said invention, and all letters patent and reissues thereof, issuing for said invention in the United States of America and in any and all foreign countries.

It is agreed that the undersigned shall be legally bound, upon request of the assignee, or its successors or assigns or a legal representative thereof, to supply all information and evidence of which the undersigned has knowledge or possession, relating to the making and practice of said invention, to testify in any legal proceeding relating thereto, to execute all instruments proper to patent the invention in the United States of America and foreign countries in the name of the assignee, and to execute all instruments proper to carry out the intent of this instrument. If the undersigned includes more than one individual, these obligations shall apply to all of the undersigned both individually and collectively.

The rights and property herein conveyed by the undersigned are free and clear of any encumbrance.

EXECUTED on \_\_\_\_\_, 20\_\_\_\_, at \_\_\_\_\_.

\_\_\_\_\_  
Maurice Bourlion

\_\_\_\_\_  
Dominique Petit

\_\_\_\_\_  
Gérard Vanacker

\_\_\_\_\_  
Witness

sign here



(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION  
EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété  
Intellectuelle  
Bureau international



(43) Date de la publication internationale  
25 août 2005 (25.08.2005)

PCT

(10) Numéro de publication internationale  
WO 2005/077282 A1

(51) Classification internationale des brevets<sup>7</sup> : A61B 17/16

(21) Numéro de la demande internationale :

PCT/FR2005/000338

(22) Date de dépôt international :

11 février 2005 (11.02.2005)

(25) Langue de dépôt :

français

(26) Langue de publication :

français

(30) Données relatives à la priorité :

0401361

11 février 2004 (11.02.2004) FR

(71) Déposant (pour tous les États désignés sauf US) :  
SPINEVISION [FR/FR]; 180, avenue Daumesnil,  
F-75012 Paris (FR).

(72) Inventeurs; et

(75) Inventeurs/Déposants (pour US seulement) :  
BOURLION, Maurice [FR/FR]; 9, rue Jean Vin-  
cent, F-42400 Saint-Chamond (FR). PETIT, Dominique  
[FR/FR]; 2, rue des Peupliers, F-62180 Verton (FR).  
VANACKER, Gérard [FR/FR]; 52, avenue François  
Adam, F-94100 Saint-Maur (FR).

(74) Mandataire : SAYETTAT, Julien; Breesé Derambure  
Majerowicz, 38, avenue de l'Opéra, F-75002 Paris (FR).

(81) États désignés (sauf indication contraire, pour tout titre de  
protection nationale disponible) : AE, AG, AL, AM, AT,

AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO,  
CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB,  
GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG,  
KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG,  
MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH,  
PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN,  
TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) États désignés (sauf indication contraire, pour tout titre  
de protection régionale disponible) : ARIPO (BW, GH,  
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,  
ZW), eurasién (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
européen (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,  
FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO,  
SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN,  
GQ, GW, ML, MR, NE, SN, TD, TO).

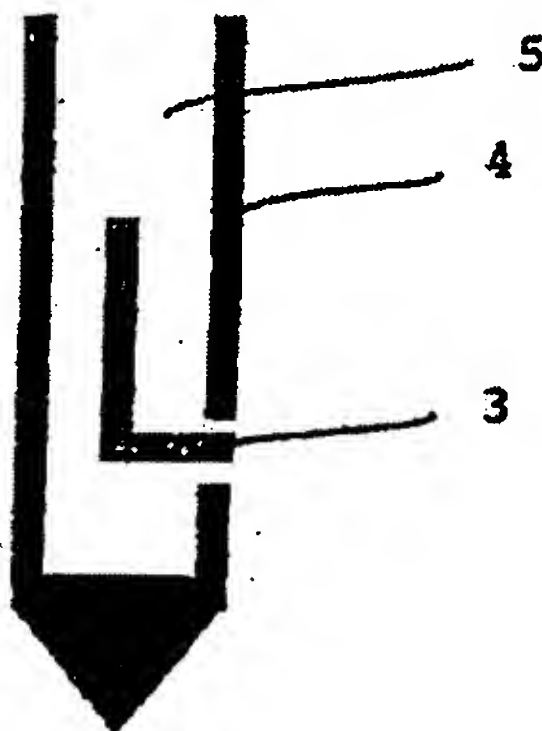
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(54) Title: EXPLORATION DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOM-  
ICAL STRUCTURE

(54) Titre : DISPOSITIF D'EXPLORATION POUR LE SUIVI DE LA PENETRATION D'UN INSTRUMENT DANS UNE  
STRUCTURE ANATOMIQUE



(57) Abstract: The invention relates to an exploration device (1) for monitoring the pen-  
etration of an instrument (2) into an anatomical structure, particularly a bone structure.  
The inventive device comprises a voltage source which powers at least two electrodes  
(3, 4) and a means for measuring the impedance between said electrodes (3, 4). The in-  
vention is characterised in that the device (1) is equipped with an angular locating means  
comprising at least one electrode (3) which comes to the surface at a point on a peripheral  
surface of the penetrating instrument (2), the position of said electrode (3) being offset  
in relation to the longitudinal axis of the instrument.

(57) Abrégé : La présente invention se rapporte à un dispositif d'exploration (1) pour  
le suivi de la pénétration d'un instrument (2) dans une structure anatomique, en particu-  
lier une structure osseuse, comportant une source de tension alimentant au moins deux  
électrodes (3, 4) et un moyen de mesure de l'impédance entre lesdites électrodes (3, 4),  
caractérisé en ce que ledit dispositif (1) comporte un moyen de localisation angulaire  
constitué par au moins une électrode (3) affleurant ponctuellement une surface périphé-  
rique dudit instrument de pénétration (2), ladite électrode (3) présentant une position  
décalée par rapport à l'axe longitudinal dudit instrument.

WO 2005/077282 A1

**DISPOSITIF D'EXPLORATION POUR LE SUIVI DE LA PÉNÉTRATION  
D'UN INSTRUMENT DANS UNE STRUCTURE ANATOMIQUE**

La présente invention se rapporte au domaine de la  
5 chirurgie rachidienne.

En chirurgie du rachis, par exemple lors du forage  
pédiculaire, il est fréquent que le cortex osseux soit  
traversé, cassé ou ébréché par l'instrument de forage,  
10 pouvant alors engendrer un mauvais positionnement des vis  
pédiculaires. Suivant ce mauvais positionnement, les vis  
pédiculaires, provoquent chez le patient des douleurs,  
paralysies, hémorragies, etc., nécessitant une nouvelle  
intervention chirurgicale, voire dans certains cas causant  
15 des dommages irréparables.

On connaît de la demande de brevet FR2835732, déposée  
par le présent demandeur, un dispositif permettant de  
suivre la pénétration d'un instrument (instrument de forage  
20 ou autre) dans la vertèbre par la mesure des différences  
d'impédance électrique au fur et à mesure de la  
pénétration, de sorte que le praticien sait, à chaque  
instant, si l'extrémité de l'instrument sort du cortex  
osseux et pénètre dans une zone de tissus mous (moelle,  
25 nerfs, tissus). Dans ce cas, le praticien modifie la  
trajectoire de l'instrument de pénétration pour revenir  
dans le cortex osseux.

Un tel dispositif permet ainsi de détecter la  
formation d'une brèche dans le cortex osseux au moment du  
30 forage.

Afin de faciliter le repositionnement de l'instrument  
de pénétration dans le cas d'une opération de forage (ou  
similaire, du type taraudage, perçage, ...), mais également  
de permettre un positionnement correct des vis pédiculaires  
35 ou de tout autre instrument chirurgical, il s'avère

nécessaire pour le praticien de connaître la position exacte des brèches formées au cours du forage.

La présente invention a donc pour objet de proposer  
5 un dispositif d'exploration permettant d'indiquer la position des brèches formées au cours d'une opération de forage (ou similaire).

À cet effet, l'invention concerne dans son  
10 acceptation la plus générale un dispositif d'exploration pour le suivi de la pénétration d'un instrument dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes et un moyen de mesure de l'impédance entre  
15 lesdites électrodes, et elle est remarquable en ce que ledit dispositif comporte un moyen de localisation angulaire constitué par au moins une électrode affleurant ponctuellement une surface périphérique dudit instrument de pénétration, la surface affleurante de ladite électrode (3)  
20 ayant une position décalée par rapport à l'axe longitudinal dudit instrument, ainsi qu'un moyen de repérage de la position de ladite au moins électrode (3).

Par affleurement ponctuel, on entend une surface de contact affleurant de manière partielle et discontinue la  
25 surface périphérique dudit instrument de pénétration. Ne constitue donc notamment pas un affleurement ponctuel, une surface de contact de forme annulaire, et par extension de forme tubulaire.

Selon que l'on souhaite effectuer des mesures  
30 latéralement ou en bout de l'instrument de pénétration ou respectivement latéralement et en bout, l'instrument de pénétration sera équipé d'une au moins électrode affleurant la surface latérale dudit instrument de pénétration et/ou d'une au moins électrodes affleurant la surface



périphérique de l'extrémité distale dudit instrument de pénétration.

Avantageusement, ladite électrode affleurante est entraînée en rotation, ladite électrode affleurante étant  
5 entraînée à une vitesse de rotation telle qu'elle balaye au moins 360 degrés par tranche d'enfoncement dudit instrument de pénétration dans la structure osseuse.

De préférence, ledit dispositif comporte une pluralité d'électrodes affleurantes fixes espacées  
10 angulairement et en ce que le moyen de mesure d'impédance délivre un signal correspondant à chacune desdites électrodes.

Avantageusement, lesdites électrodes consistent en des contacts ponctuels espacés longitudinalement et  
15 angulairement.

Avantageusement, lesdites électrodes sont formées de bandes longitudinales.

Selon une configuration particulière de l'invention, les électrodes sont réparties autour de l'axe longitudinal  
20 de l'instrument de pénétration.

Avantageusement, les électrodes sont disposées symétriquement par rapport à l'axe longitudinal dudit instrument de pénétration.

Avantageusement, lesdites électrodes sont constituées  
25 par des tiges conductrices de section circulaire, semi-annulaire, rectangulaire et/ou triangulaire. De même, elles peuvent être constituées par des tiges conductrices excentrées.

Selon le domaine d'intervention dans lequel est  
30 utilisé l'instrument de pénétration, ledit dispositif pourra comporter à son(ses) extrémité(s) distale(s) au moins une électrode. Avantageusement, ledit dispositif comporte deux électrodes disposées à l'extrémité distale dudit instrument de pénétration, lesdites électrodes étant

constitués par des tiges conductrices de section circulaire concentrique.

Avantageusement, ledit moyen de repérage consiste en un marquage visuel porté de préférence sur la poignée dudit  
5 dispositif d'exploration. Selon un mode de réalisation particulier de l'invention, ladite poignée (6) constitue ledit moyen de repérage.

Avantageusement, ledit dispositif comporte en outre un canal central pour le passage d'un instrument  
10 additionnel.

On comprendra mieux l'invention à l'aide de la description, faite ci-après à titre purement explicatif, en référence aux figures annexées :

- 15 - la figure 1 illustre une vue schématisée d'un dispositif d'exploration selon l'invention ;
- la figure 2 illustre une vue en coupe frontale de l'extrémité distale de l'instrument de pénétration selon une première configuration de l'invention ;
- 20 - la figure 3 illustre une vue en coupe longitudinale de l'instrument de pénétration selon une deuxième configuration de l'invention ;
- la figure 4 illustre une vue en coupe frontale de l'extrémité distale de l'instrument de pénétration selon  
25 une troisième configuration de l'invention ;
- la figure 5 illustre une vue en perspective de l'instrument de pénétration selon une quatrième configuration de l'invention ; et
- la figure 6 illustre une vue en coupe  
30 longitudinale de l'instrument de pénétration selon une cinquième configuration de l'invention.

Le dispositif d'exploration (1) selon l'invention, illustré figure 1, est un dispositif permettant le suivi de  
35 la pénétration d'un instrument (2) dans les structures

osseuses d'un corps humain ou animal, lesdites structures présentant au moins deux zones d'impédance électrique différentes.

Le dispositif d'exploration (1) comporte une source  
5 de tension (non représentée) alimentant au moins deux électrodes et un moyen de mesure de l'impédance (non représenté) entre lesdites électrodes.

L'une au moins desdites électrodes est disposée sur ledit instrument de pénétration (2).

10 Ledit dispositif comporte en outre des moyens de signalisation produisant un signal lors de la détection, par l'impédancemètre, d'une variation d'impédance, et donc de la présence d'une brèche. Lesdits moyens de signalisation consistent à l'émission d'un signal visuel,  
15 tel qu'un témoin lumineux, d'un signal sonore, et/ou d'un signal tactile (vibreux, -).

Selon un mode avantageux de réalisation de l'invention, ledit dispositif comporte également des moyens d'acquisition et de visualisation de la position des  
20 brèches au cours de la pénétration de l'instrument (2) dans la structure osseuse.

Selon les applications envisagées, l'instrument de pénétration (2) peut être soit fixe, soit entraîné en  
25 rotation manuellement ou par des moyens d'entraînement du type moteur (non représentés).

Ainsi, il pourra s'agir, dans la première configuration, par exemple d'une sonde, d'une pointe carrée, d'une spatule, d'une curette ou autre, et dans la  
30 seconde configuration, par exemple d'une vis, d'une mèche de forage, de taraudage, ou autre.

Dans la partie ci-après, l'instrument de pénétration (2) consiste en une sonde (2). Cependant les configurations présentées sont bien entendu applicables aux autres  
35 instruments de pénétration mentionnés ci-dessus.

La figure 2 illustre une première configuration de la sonde (2) constituant ledit dispositif d'exploration (1).

Dans cette première configuration, l'instrument de  
5 pénétration (2) présente au niveau de son extrémité distale, deux électrodes (3, 4) de section circulaire et excentrique, l'électrode (3) étant entourée mais séparée de l'électrode (4) par une couronne d'isolant (5).

L'électrode (3) constitue, dans cet exemple de  
10 réalisation, le pôle positif dudit dispositif électronique, le pôle négatif dudit dispositif électronique étant constitué par l'électrode (4). Il est bien entendu évident qu'il ne s'agit ici que d'un exemple de réalisation, et que l'homme du métier pourra réaliser un dispositif  
15 électronique dont le pôle positif sera constitué par l'électrode (4) et le pôle négatif par l'électrode (3) sans pour autant sortir de l'invention.

Chaque électrode (3, 4) est disposée de sorte à affleurer la surface dudit instrument de pénétration (2).

20 Afin d'éviter toute perturbation du signal, la surface de l'électrode centrale ou interne (3) affleurant la surface dudit instrument de pénétration (2) reste relativement petite par rapport aux dimensions du trou effectué dans le cortex osseux lors de l'opération de  
25 forage (ou autre).

La position de l'électrode (3) est repérée par un marquage spécifique sur ledit dispositif d'exploration (1). Avantageusement, le marquage est effectué au moyen de la poignée (6) dudit dispositif d'exploration (1). Il pourra  
30 s'agir par exemple d'une signalisation visuelle, comme par exemple une flèche, représentée sur la poignée (6). Le marquage pourra être réalisé également au moyen directement de la poignée (6), comme par exemple une forme spécifique de ladite la poignée (6).



Ainsi, lors de la pénétration de l'instrument (2) dans la structure osseuse perforée, un signal est émis par lesdits moyens de signalisation lorsque une variation d'impédance mesurée entre les électrodes (3, 4) est  
5 détectée par l'impédancemètre, indiquant la présence d'une brèche.

Suite à cette détection, les moyens de signalisation émettent un signal d'alerte (visuel, sonore, ou tactile). Le praticien sait à ce moment que l'électrode (3) de  
10 l'instrument de pénétration est positionnée devant une brèche.

Le praticien détermine alors la direction de la brèche grâce au repère correspondant au positionnement de l'électrode (3) marqué sur la poignée (6) dudit dispositif  
15 d'exploration (1).

Afin de permettre un balayage complet de la structure osseuse, ledit instrument (2) de pénétration est animé d'un mouvement de rotation, la vitesse de rotation étant supérieure à la vitesse d'avancement de l'instrument (2) de  
20 pénétration dans la structure osseuse. En d'autres termes, la vitesse de rotation dudit instrument (2) sera telle que ledit instrument (2) de pénétration balayera au moins 360 degrés par tranche d'enfoncement.

25 La figure 3 illustre une seconde configuration de la sonde (2) constituant ledit dispositif d'exploration (1), laquelle permet de détecter des brèches disposées latéralement par rapport au corps dudit instrument (2) de pénétration.

30 Dans cette seconde configuration, l'électrode (3) est positionnée dans ledit instrument de pénétration (2) de sorte à affleurer ponctuellement la surface latérale dudit instrument (2) de pénétration.

L'électrode (4), quant à elle, est répartie sur le  
35 reste de la surface latérale restante dudit instrument (2)

de pénétration, y compris son extrémité distale. Lesdites électrodes (3, 4) sont séparées l'une de l'autre par un isolant (5).

Le principe de détection et de détermination de la direction de la brèche est identique à celui exposé précédemment.

La figure 4 illustre une troisième configuration de la sonde (2) constituant ledit dispositif d'exploration (1), laquelle permet de détecter des brèches disposées à l'extrémité dudit instrument (2) de pénétration.

Dans cette troisième configuration, l'instrument de pénétration (2) présente au niveau de son extrémité distale trois électrodes (7, 8, 9) de section triangulaire sensiblement identiques. Lesdites électrodes (7, 8, 9), réparties autour de l'axe longitudinalement de l'instrument (2) de pénétration, sont espacées angulairement. Avantageusement, l'espacement angulaire est identique.

La position des électrodes (7, 8, 9) étant connue par construction, leur disposition sur l'extrémité distale donne des indications sur la position des brèches. En effet, la brèche détectée sera située entre les deux électrodes pour lesquelles un signal est émis.

Le nombre et la forme triangulaire des électrodes étant donné ici à titre d'exemple, il est entendu que ledit instrument (2) de pénétration peut présenter des électrodes en nombre supérieur et de forme autre que triangulaire. La détermination de la direction des brèches sera d'autant plus précise que le nombre d'électrodes réparties à l'extrémité dudit instrument (2) sera élevé.

La figure 5 illustre une autre configuration de la sonde (2), permettant de détecter des brèches disposées à l'extrémité dudit instrument (2) de pénétration, mais également latéralement.

Dans cette configuration, ledit instrument (2) de pénétration est constitué d'une pluralité d'électrodes disposées affleurantes à la surface latérale dudit instrument (2) de pénétration et à l'extrémité distale dudit instrument (2).

La position de chaque électrode étant connue, il est alors possible, comme pour la troisième configuration, de déterminer la position de la brèche par l'émission d'un signal par l'impédancemètre correspondant à l'électrode positionnée face à la brèche.

Dans les configurations précédemment présentées, les moyens de détermination de la position des brèches consistent en des électrodes fixes. Selon une configuration particulière de l'instrument (2) de pénétration (non représentée), la détermination des brèches pourra être également effectuée au moyen d'une ou plusieurs électrodes mobiles.

De même, dans les exemples précédents, les électrodes (3, 4) sont portées respectivement par ledit instrument de pénétration (2). Il va de soi que ledit instrument de pénétration (2) pourra être muni d'une seule électrode (3), l'autre électrode étant positionnée sur le patient, et plus particulièrement sur une surface autre que la plaie opératoire, sans pour autant sortir du champ de l'invention.

Comme cela a été précisé précédemment, les configurations présentées restent applicables aux autres instruments de pénétration mentionnés ci-dessus.

En particulier, dans le cas où l'instrument (2) de pénétration consiste en un élément de forage, ledit instrument (2) de pénétration pourra avantageusement comporter au moins une électrode (13) affleurant la surface



latérale dudit instrument (2) de pénétration, ainsi que deux électrodes (10, 11) disposées concentriquement à l'extrémité distale dudit instrument (2) de pénétration (figure 6). Il sera ainsi possible, de part la  
5 configuration dudit instrument (2) de pénétration de déterminer la présence et la direction d'une brèche au  
moyen des électrodes (11 et 13), ainsi que de prévenir une éventuelle perforation du cortex osseux au moyen des électrodes (10 et 11). A cet effet, il devra être évité de  
10 positionner une électrode latérale consistant en une tige allant jusqu'à l'extrémité distale. Il serait en effet impossible, avec une telle configuration, de savoir si la zone détectée par les électrodes est latérale ou distale.

15 L'invention est décrite dans ce qui précède à titre d'exemple. Il est entendu que l'homme du métier est à même de réaliser différentes variantes de l'invention sans pour autant sortir du cadre du brevet.

REVENDICATIONS

1. Dispositif d'exploration (1) pour le suivi de la pénétration d'un instrument (2) dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes (3, 4) et un moyen de mesure de l'impédance entre lesdites électrodes (3, 4), caractérisé en ce que ledit dispositif (1) comporte un moyen de localisation angulaire constitué par au moins une électrode (3) affleurant ponctuellement une surface périphérique dudit instrument de pénétration (2), la surface affleurante de ladite électrode (3) ayant une position décalée par rapport à l'axe longitudinal dudit instrument, ainsi qu'un moyen de repérage de la position de ladite au moins électrode (3).

2. Dispositif d'exploration (1) selon la revendication 1, caractérisé en ce que ladite électrode (3) affleure ponctuellement la surface latérale dudit instrument de pénétration (2).

3. Dispositif d'exploration (1) selon la revendication 1 ou la revendication 2, caractérisé en ce que ladite électrode (3) affleure ponctuellement la surface périphérique de l'extrémité distale dudit instrument de pénétration (2).

4. Dispositif d'exploration (1) selon l'une quelconque des revendications précédentes, caractérisé en ce que ladite électrode (3) affleurante est entraînée en rotation.

5. Dispositif d'exploration (1) selon la revendication précédente, caractérisé en ce que ladite électrode (3) affleurante est entraînée à une vitesse de

rotation telle que ladite électrode (3) balaye au moins 360 degrés par tranche d'enfoncement dudit instrument de pénétration (2) dans la structure osseuse.

5           6. Dispositif d'exploration (1) selon la  
revendication 1, caractérisé en ce qu'il comporte une  
pluralité d'électrodes (3, 4, 7, 8, 9) affleurantes fixes  
espacées angulairement et en ce que le moyen de mesure  
d'impédance délivre un signal correspondant à chacune  
10 desdites électrodes (3, 4, 7, 8, 9).

7. Dispositif d'exploration (1) selon la  
revendication 6, caractérisé en ce que lesdites électrodes  
(3, 4, 7, 8, 9) consistent en des contacts ponctuels  
15 espacés longitudinalement et angulairement.

8. Dispositif d'exploration (1) selon la  
revendication 6, caractérisé en ce que lesdites électrodes  
(3, 4, 7, 8, 9) sont formées de bandes longitudinales.  
20

9. Dispositif d'exploration (1) selon l'une  
quelconque des revendications 6 à 8, caractérisé en ce que  
les électrodes (3, 4, 7, 8, 9) sont réparties autour de  
l'axe longitudinal de l'instrument de pénétration (2).  
25

10. Dispositif d'exploration (1) selon l'une  
quelconque des revendications 6 à 9, caractérisé en ce que  
les électrodes (3, 4, 7, 8, 9) sont disposées  
symétriquement par rapport à l'axe longitudinal dudit  
30 instrument de pénétration (2).

11. Dispositif d'exploration (1) selon l'une  
quelconque des revendications 6 à 10, caractérisé en ce que  
lesdites électrodes (3, 4, 7, 8, 9) sont constituées par

des tiges conductrices de section circulaire, semi-annulaire, rectangulaire et/ou triangulaire.

12. Dispositif d'exploration (1) selon l'une  
5 quelconque des revendications 6 à 11, caractérisé en ce que  
lesdites électrodes sont constituées par des tiges  
conductrices excentrées.

13. Dispositif d'exploration (1) selon l'une  
10 quelconque des revendications précédentes, caractérisé en  
ce que ledit dispositif comporte (1) en outre au moins une  
électrode disposée à l'extrémité distale dudit instrument  
de pénétration.

14. Dispositif d'exploration (1) selon la  
15 revendication précédente, caractérisé en ce que ledit  
dispositif (1) comporte deux électrodes disposées à  
l'extrémité distale dudit instrument de pénétration,  
lesdites électrodes étant constituées par des tiges  
20 conductrices de section circulaire concentrique.

15. Dispositif d'exploration (1) selon l'une  
quelconque des revendications précédentes, caractérisé en  
ce que ledit moyen de repérage consiste en un marquage  
25 visuel porté de préférence sur la poignée (6) dudit  
dispositif d'exploration (1).

16. Dispositif d'exploration (1) selon l'une  
quelconque des revendications précédentes, caractérisé en  
30 ce que le dispositif d'exploration (1) comporte une poignée  
(6) constituant ledit moyen de repérage.

17. Dispositif d'exploration (1) selon l'une  
quelconque des revendications précédentes, caractérisé en

ce qu'il comporte une poignée constituant ledit moyen de repérage.

18. Dispositif d'exploration (1) selon l'une  
5 quelconque des revendications précédentes, caractérisé en  
~~ce qu'il comporte un canal central pour le passage d'un~~  
instrument additionnel.

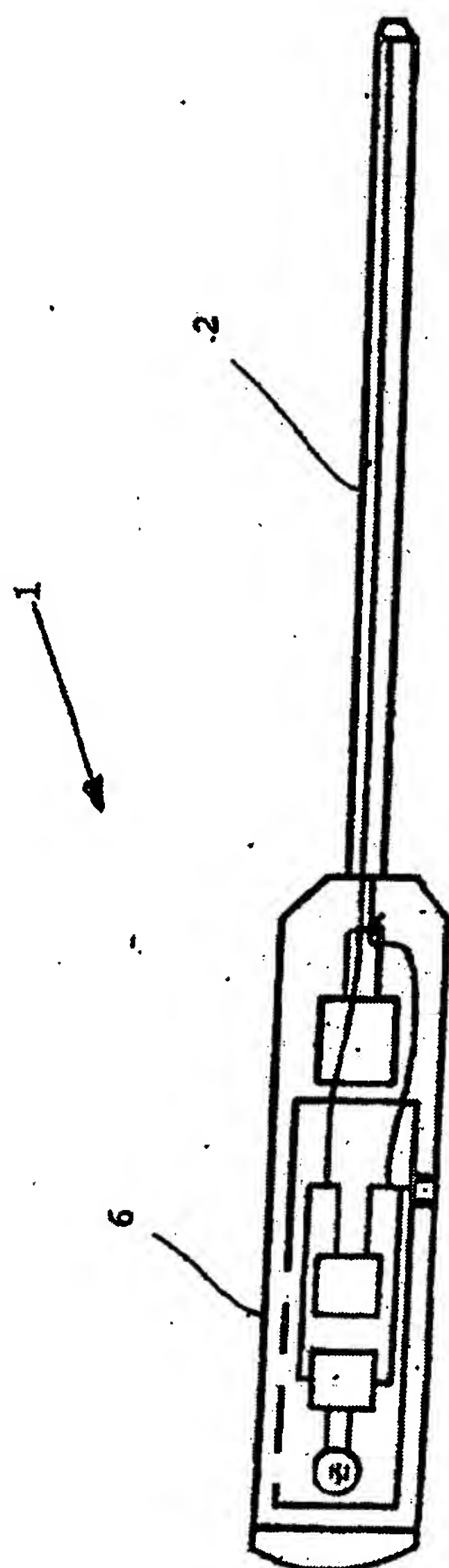


Fig. 1

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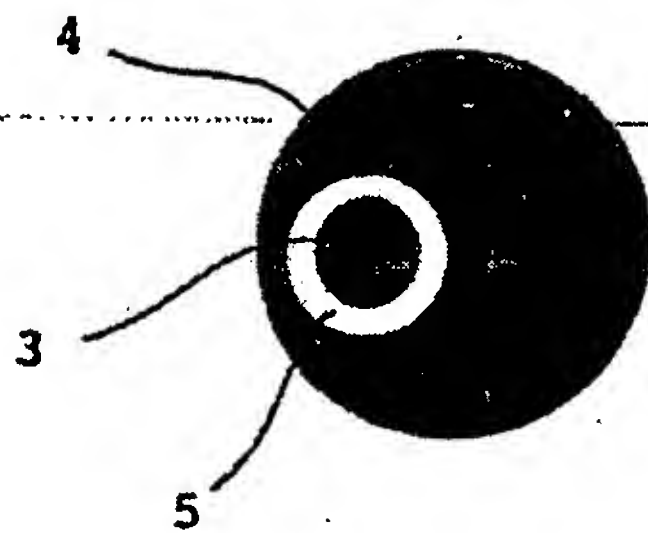


Fig. 2

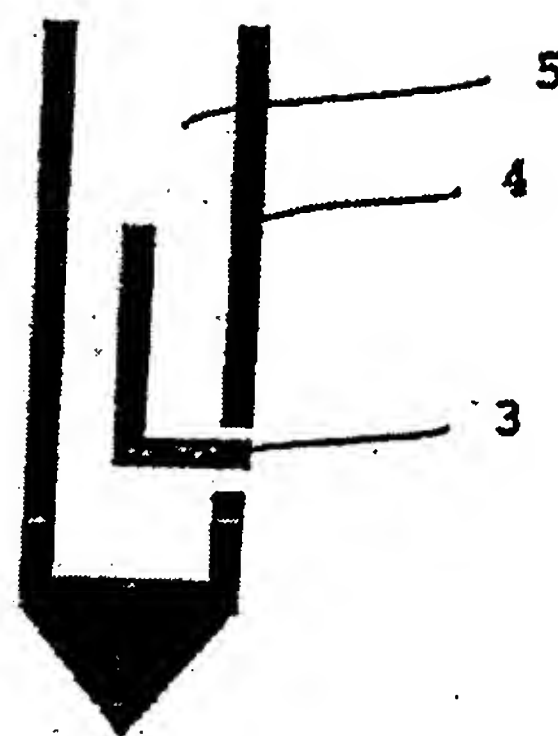


Fig. 3



3/4

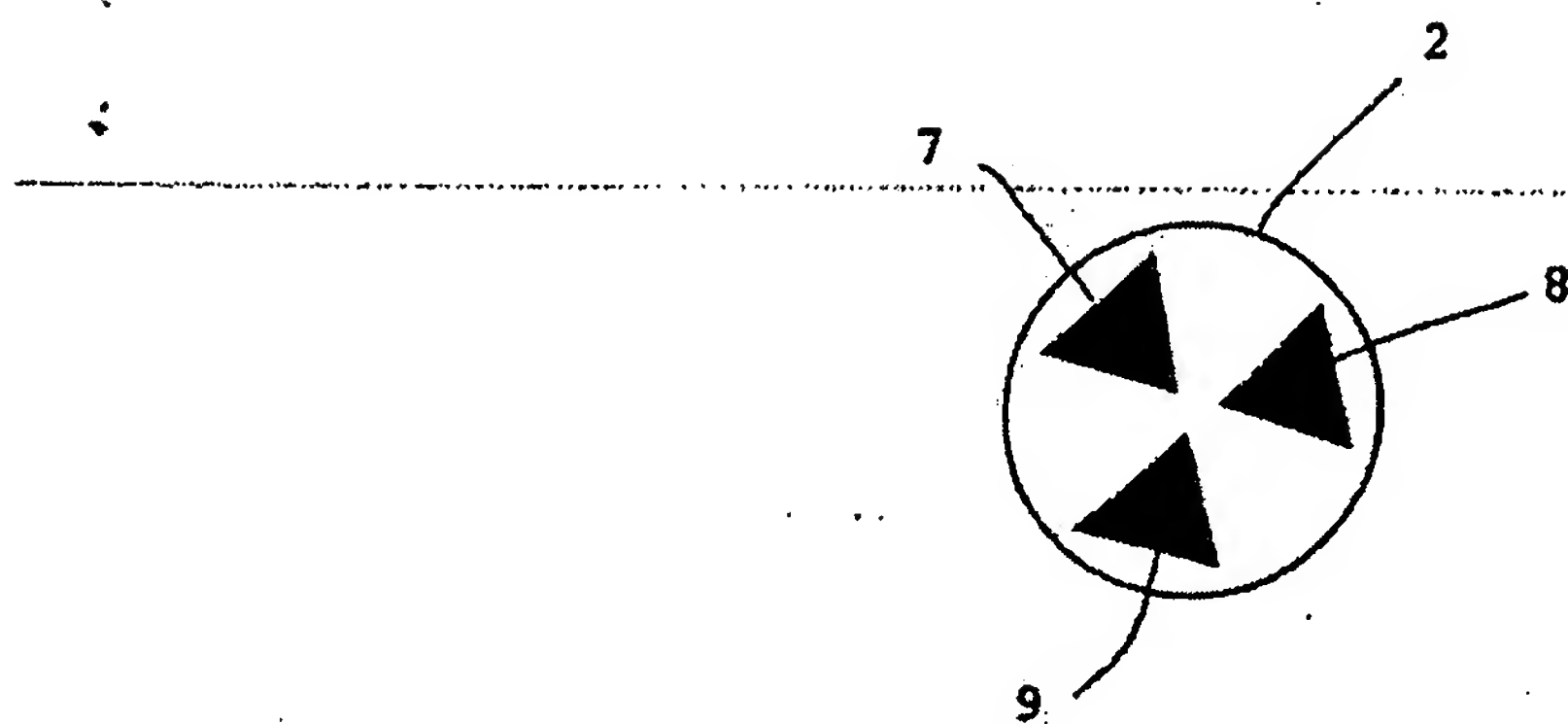


Fig. 4

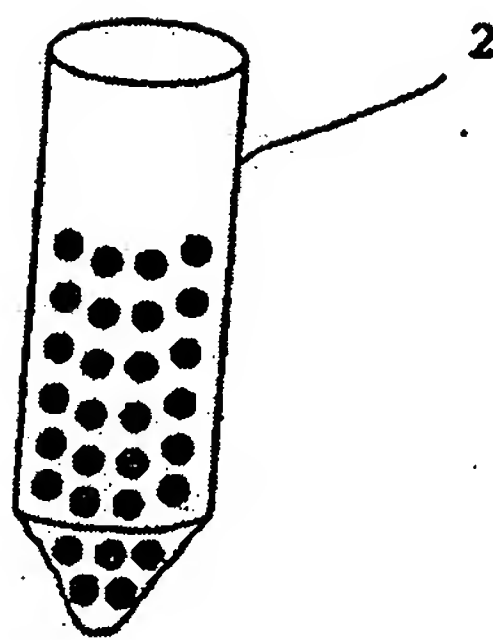


Fig. 5

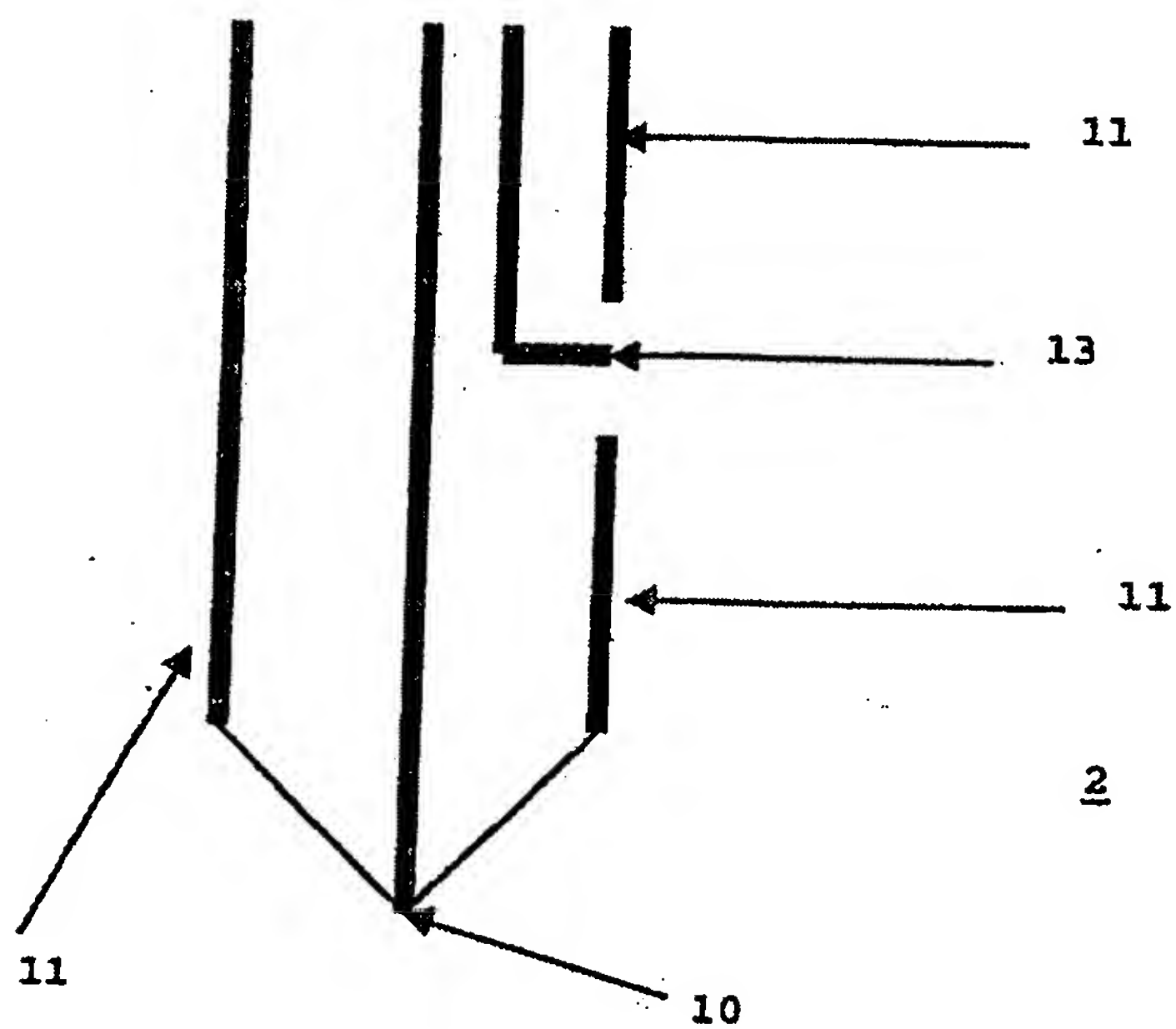


Fig. 6

EXPLORATION DEVICE TO MONITOR THE PENETRATION  
OF AN INSTRUMENT IN AN ANATOMIC STRUCTURE

[0001] The present invention refers to the field of spinal surgery.

[0002] In surgery of the spine, for example for pedicular drilling, the bone cortex is often crossed, broken or damaged by the drilling instrument, that may then lead to the poor positioning of the pedicular screws. Following this poor positioning, the pedicular screws, inducing pain, paralysis, haemorrhage, etc. in the patient, may require another surgical intervention or, in certain cases, cause irreparable damage.

[0003] We are familiar with patent application FR2835732, filed by the present applicant, a device to monitor the penetration of an instrument (dill or other type of instrument) in the vertebra by measuring the differences in the electrical impedance during the penetration, so that the practitioner is constantly aware whether the end of the instrument is leaving the bone cortex and penetrating into a zone of soft tissue (marrow, nerves, tissue). In this case, the practitioner modifies the path of the penetration instrument in order to return to the bone cortex.

[0004] Such a device may also be used to detect the formation of a gap in the bone cortex during drilling.

[0005] To facilitate the repositioning of the penetration instrument during a drilling operation (or similar type of operation such as tapping, boring, etc.), but also to enable the proper positioning of the pedicular screw or any other surgical instrument, the practitioner has to know the exact position of the gaps formed during the drilling.

[0006] The present invention therefore aims at proposing an exploration device indicating the position of the gaps formed during a drilling (or similar) operation.

[0007] For this purpose, the invention involves, according to its most general acceptance, an exploration device to monitor the penetration of an instrument in an anatomic structure, in particular bone structure, comprising a source of voltage supplying at least two electrodes and a means to measure the impedance between the aforementioned electrodes, and is it remarkable in that the aforementioned device includes a means of angular location formed by at least one electrode punctually coinciding with a peripheral surface of the aforementioned penetration instrument, the coinciding surface of the aforementioned electrode (3) whose position is set off from the longitudinal axis of the aforementioned instrument, as well as a means to detect the position of the aforementioned electrode (3).

[0008] By punctual coincidence, we mean a contact surface partially and discontinually coinciding with the peripheral surface of the aforementioned penetration instrument. In particular, an angular contact surface, and by extension a tubular shape are not considered as providing punctual coincidence.

[0009] Depending on whether one desires taking lateral readings or readings at the end of the penetration instrument or laterally and at the end, respectively, the penetration instrument will be equipped with at least one electrode coinciding with the lateral surface of the aforementioned penetration instrument and/or at least one electrode coinciding with the peripheral surface of the distal end of the aforementioned penetration instrument.

[0010] Advantageously, the aforementioned coinciding electrode is driven in rotation, the aforementioned coinciding electrode being driven at speed of rotation so that it sweeps at least 360 degrees per level of insertion of the aforementioned penetration instrument in the bone structure.

- [0011] Preferably, the aforementioned device comprises a plurality of angularly spaced coinciding fixed electrodes and that the means to measure the impedance delivers a signal corresponding to each of the aforementioned electrodes.
- [0012] Advantageously, the aforementioned electrodes consist of punctual contacts longitudinally and angularly spaced out.
- [0013] Advantageously, the aforementioned electrodes are formed by longitudinal strips.
- [0014] According to one specific configuration of the invention, the electrodes are distributed around the longitudinal axis of the penetration instrument.
- [0015] Advantageously, the electrodes are symmetrically arranged with respect to the longitudinal axis of the aforementioned penetration instrument.
- [0016] Advantageously, the aforementioned electrodes consist of conducting rods of circular, semi-annular, rectangular and/or triangular section. In addition, they may consist of eccentric conducting rods.
- [0017] According to the realm of intervention in which the penetration instrument is used, the aforementioned device may comprise at least one electrode at its distal end(s). Advantageously, the aforementioned device comprises two electrodes arranged at the distal end of the aforementioned penetration instrument, the aforementioned electrodes consisting of conducting rods of concentric circular section.
- [0018] Advantageously, the aforementioned means of detection consists of visual marking preferably on the handle of the aforementioned exploration device. According to one specific means of creation of the device, the aforementioned handle (6) forms the aforementioned means of detection.



[0019] Advantageously, the aforementioned device also comprises a central channel for the passage of an additional instrument.

[0020] Now, the invention will better be understood using the following description that is only provided for explanatory purposes, with reference to the appended figures:

- figure 1 illustrates a diagram of an exploration device according to the invention;
- figure 2 illustrates a front cutaway view of the distal end of the penetration instrument according to a first configuration of the invention;
- figure 3 illustrates a longitudinal cutaway view of the penetration instrument according to a second configuration of the invention;
- figure 4 illustrates a front cutaway view of the distal end of the penetration instrument according to a third configuration of the invention;
- figure 5 illustrates a perspective view of the penetration instrument according to a fourth configuration of the invention; and
- figure 6 illustrates a longitudinal cutaway view of the penetration instrument according to a fifth configuration of the invention.

[0021] According to the invention, the exploration device (1), illustrated in figure 1, is a device enabling the monitoring of the penetration of an instrument (2) in the bone structures of a human or animal body, the aforementioned structures presenting at least two different zones of electrical impedance.

[0022] The exploration device (1) comprises a source of voltage (not represented) supplying at least two electrodes and a means to measure the impedance (not represented) between the aforementioned electrodes.

[0023] At least one of the aforementioned electrodes is found on the aforementioned penetration instrument (2).

[0024] The aforementioned device also comprises means of signalling producing a signal at the time of detection, by impedometer, a variation of impedance, and therefore the presence of a gap. The aforementioned means of signalling consist of the emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator, etc.).

[0025] According to one advantageous mode of creation of the invention, the aforementioned device also comprises means for the acquisition and visualisation of the position of the gaps during the penetration of the instrument (2) in the bone structure.

[0026] According to the applications considered, the penetration instrument (2) may either be fixed, or manually driven in rotation by means of drive of the motor type (not represented).

[0027] Therefore, it may consist, in the first configuration, for example of a probe, a square tip, a spatula, a curette or other, and in the second configuration, for example of a screw, a drill, a tap, or other.

[0028] In the following section, the penetration instrument (2) consists of a probe (2). However, the configurations presented are of course applicable to the other penetration instruments mentioned above.

[0029] Figure 2 illustrates the first configuration of the probe (2) forming the aforementioned exploration device (1).

[0030] In this first configuration, the penetration instrument (2) presents two eccentric electrodes (3, 4) of circular section at its distal end, electrode (3) being surrounded but separated from electrode (4) by an insulation ring (5).

[0031] In this example, electrode (3) comprises the positive pole of the aforementioned electronic device, the negative pole of the aforementioned electronic device consisting of the electrode (4). It is obvious that this is only one example of a creation and that the man of the art may create an electronic device whose positive pole consists of the electrode (4) and the negative pole of the electrode (3) without going beyond the invention.

[0032] Each electrode (3, 4) is arranged so as to coincide with the surface of the aforementioned penetration instrument (2).

[0033] To avoid any disturbance of the signal, the surface of the central or internal electrode (3) coinciding with the surface of the aforementioned penetration instrument (2) remains relatively small with respect to the dimensions of the hole made in the bone cortex during the drilling (or other) operation.

[0034] The position of the electrode (3) is detected by specific marking on the aforementioned exploration device (1). Advantageously, the marking is carried out by means of the handle (6) of the aforementioned exploration device (1). It may, for example, consist of a visual signal, for example an arrow, represented on the handle (6). The marking may also consist of any means directly on the handle (6), such as, for example, a specific shape of the aforementioned handle (6).

[0035] Therefore, during the penetration of the instrument (2) in the perforated bone structure, a signal is given off by the aforementioned means of signalling when a variation in impedance measured between the electrodes (3, 4) is detected by the impedometer, indicating the presence of a gap.

[0036] Following this detection, the means of signalling emit a warning signal (visual, sound or tactile). The practitioner then knows that the electrode (3) from the penetration instrument is positioned in front of a gap.

[0037] The practitioner then determines the direction of the gap with the mark corresponding to the position of the electrode (3) marked on the handle (6) of the aforementioned exploration device (1).

[0038] In order to enable full scanning of the bone structure, the aforementioned penetration instrument (2) is endowed with a movement of rotation, the speed of rotation exceeding the speed of progress of the penetration instrument (2) in the bone structure. In other terms, the speed of rotation of the aforementioned instrument (2) is such that the aforementioned penetration instrument (2) sweeps at least 360 degrees by level of penetration.

[0039] Figure 3 illustrates a second configuration of the probe (2) comprising the aforementioned exploration device (1), which enables the detection of gaps laterally arranged with respect to the body of the aforementioned penetration instrument (2).

[0040] In this second configuration, the electrode (3) is positioned in the aforementioned penetration instrument (2) so as to punctually coincide with the lateral surface of the aforementioned penetration instrument (2).

[0041] As for the electrode (4), it is distributed on the rest of the lateral surface of the aforementioned penetration instrument (2), including its distal end. The aforementioned electrodes (3, 4) are separated from each other by an insulant (5).

[0042] The principle of detection and the determination of the direction of the gap are identical to that described above.

[0043] Figure 4 illustrates a third configuration of the probe (2) comprising the aforementioned exploration device (1), which enables detection of gaps arranged at the end of the aforementioned penetration instrument (2).

[0044] In this third configuration, the penetration instrument (2) presents three electrodes (7, 8, 9) of sensibly identical triangular section at the distal end. The aforementioned electrodes (7, 8, 9) distributed around the longitudinal axis of the penetration instrument (2) are angularly spaced. Advantageously, the angular space is identical.

[0045] Since the position of the electrodes (7, 8, 9) is known by the construction, their arrangement on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes for which a signal is emitted.

[0046] Since the number and triangular shape of the electrodes is given here by way of example, it is understood that the aforementioned penetration instrument (2) may present a greater number of electrodes and a shape other than triangular. The determination of the direction of the gaps is all the more exact when the number of electrodes distributed at the end of the aforementioned instrument (2) is higher.

[0047] Figure 5 illustrates another configuration of the probe (2), enabling detection of the gaps arranged at the end of the aforementioned penetration instrument (2), but also laterally.

[0048] In this configuration, the aforementioned penetration instrument (2) consists of a plurality of electrodes coinciding with the lateral surface of the aforementioned penetration instrument (2) and at the distal end of the aforementioned penetration instrument (2).

[0049] Since the position of each electrode is known, it is then possible, as in the third configuration, to determine the position of the gap by the emission of a signal by the impedometer corresponding to the electrode positioned in front of the gap.



[0050] In the configurations presented above, the means to determine the position of the gaps consist of fixed electrodes. According to a specific configuration of the aforementioned penetration instrument (2) (not represented), the gaps may also be determined by means of one or several mobile electrodes.

[0051] In addition, in the previous examples, the electrodes (3, 4) are respectively carried by the aforementioned penetration instrument (2). Of course, the aforementioned penetration instrument (2) may be equipped with only one electrode (3), the other electrode being positioned on the patient, and more specifically, on a surface other than the surgical wound, without going beyond the field of the invention.

[0052] As specified above, the configurations presented remain applicable to the other penetration instruments mentioned above.

[0053] In particular, in the case where the penetration instrument (2) consists of a drill element, the aforementioned penetration instrument (2) may advantageously comprise at least one electrode (13) coinciding with the lateral surface of the aforementioned penetration instrument (2), as well as two electrodes (10, 11) concentrically arranged at the distal end of the aforementioned penetration instrument (2) (figure 6). It is therefore possible, due to the configuration of the aforementioned penetration instrument (2) to determine the presence and direction of a gap by means of electrodes (11 and 13), as well as prevent any possible perforation of the bone cortex using electrodes (10 and 11). For this purpose, the positioning of a lateral electrode consisting of a rod extending to the distal end should be avoided. In fact, it would be impossible, with such a configuration, to know whether the zone detected by the electrodes is lateral or distal.

[0054] The invention is described above by way of example. It is understood that the man of the art is able to create different variants of the invention without going outside of the patent.

CLAIMS

1. Exploration device (1) to monitor the penetration of an instrument (2) in an anatomic structure, in particular a bone structure, comprising a source of voltage supplying at least two electrodes (3, 4) and a means to measure the impedance between the aforementioned electrodes (3, 4), characterised in that the aforementioned device (1) comprises a means of angular location formed by at least one electrode (3) punctually coinciding with a peripheral surface of the aforementioned penetration instrument (2), the coinciding surface of the aforementioned electrode (3) having a position set off from the longitudinal axis of the aforementioned instrument, as well as a means of detection of the position of the at least one aforementioned electrode (3).
2. Exploration device (1) according to claim 1, characterised in that the aforementioned electrode (3) punctually coincides with the lateral surface of the aforementioned penetration instrument (2).
3. Exploration device (1) according to claim 1 or claim 2, characterised in that the aforementioned electrode (3) punctually coincides with the peripheral surface of the distal end of the aforementioned penetration instrument (2).
4. Exploration device (1) according to any of the previous claims, characterised in that the aforementioned coinciding electrode (3) is moved in rotation.

5. Exploration device (1) according to the previous claim, characterised in that the aforementioned coinciding electrode (3) is driven at a speed of rotation so that the aforementioned electrode (3) sweeps at least 360 degrees per level of drilling of the aforementioned penetration instrument (2) in the bone structure.

6. Exploration device (1) according to claim 1, characterised in that comprises a plurality of coinciding angularly spaced fixed electrodes (3, 4, 7, 8, 9) and that the means of measurement of the impedance delivers a signal corresponding to each of the aforementioned electrodes (3, 4, 7, 8, 9).

7. Exploration device (1) according to claim 6, characterised in that the aforementioned electrodes (3, 4, 7, 8, 9) consist of longitudinally and angularly spaced punctual contacts.

8. Exploration device (1) according to claim 6, characterised in that the aforementioned electrodes (3, 4, 7, 8, 9) are formed of longitudinal strips.

9. Exploration device (1) according to any of claims 6 to 8, characterised in that the electrodes (3, 4, 7, 8, 9) are distributed around the longitudinal axis of the penetration instrument (2).

10. Exploration device (1) according to any of claims 6 to 9, characterised in that the electrodes (3, 4, 7, 8, 9) are symmetrically arranged with respect to the longitudinal axis of the aforementioned penetration instrument (2).
11. Exploration device (1) according to any of claims 6 to 10, characterised in that the aforementioned electrodes (3, 4, 7, 8, 9) consist of conducting rods of circular, semi-annular, rectangular and/or triangular section.
12. Exploration device (1) according to any of claims 6 to 11, characterised in that the aforementioned electrodes are formed by eccentric conducting rods.
13. Exploration device (1) according to any of the previous claims, characterised in that the aforementioned device (1) also comprises at least one electrode arranged at the distal end of the aforementioned penetration instrument.
14. Exploration device (1) according to the previous claim, characterised in that the aforementioned device (1) comprises two electrodes arranged at the distal end of the aforementioned penetration instrument, the aforementioned electrodes consisting of conducting rods of concentric circular section.
15. Exploration device (1) according to any of the previous claims, characterised in that the aforementioned means of detection consists of a visual marking preferably on the handle (6) of the aforementioned exploration device (1).

16. Exploration device (1) according to any of the previous claims, characterised in that the exploration device (1) comprises a handle (6) forming the aforementioned means of detection.

17. Exploration device (1) according to any of the previous claims, characterised in that it comprises a handle forming the aforementioned means of detection.

18. Exploration device (1) according to any of the previous claims, characterised in that it comprises a central channel for the passage of an additional instrument.



EXPLORATION DEVICE TO MONITOR THE...  
Inventors: Maurice Bourdon et al.  
EMC: EV 348524558 US  
Sheet 1 of 4  
Docket No.: BDM-06-1208  
DLA Piper Rudnick Gray Cary US LLP: (215) 656-3381

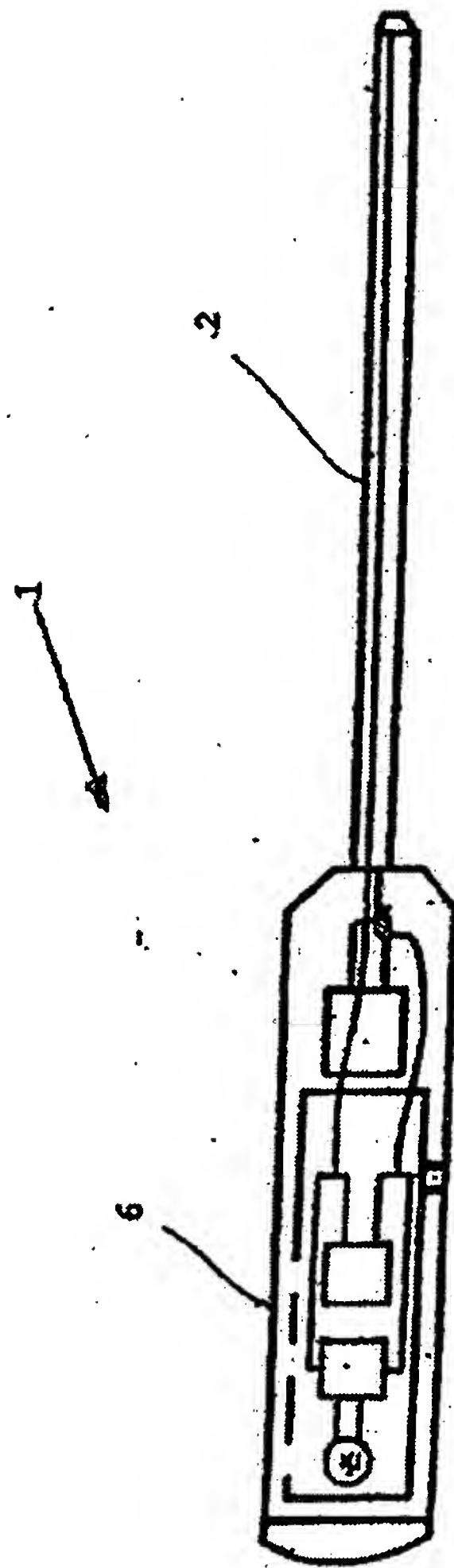


Fig. 1

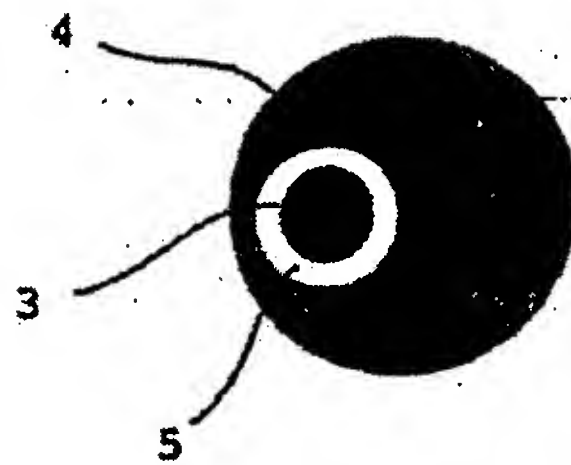


Fig. 2

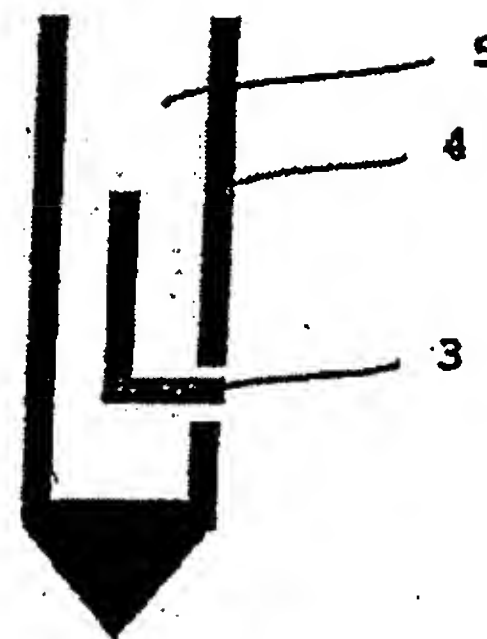


Fig. 3

EXPLORATION DEVICE TO MONITOR THE...  
inventors: Maurice Bourillon et al.  
SMC: EV 548514558 US  
Sheet 3 of 4  
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DLA Piper Rudnick Gray Cary US LLP: (215) 656-3381

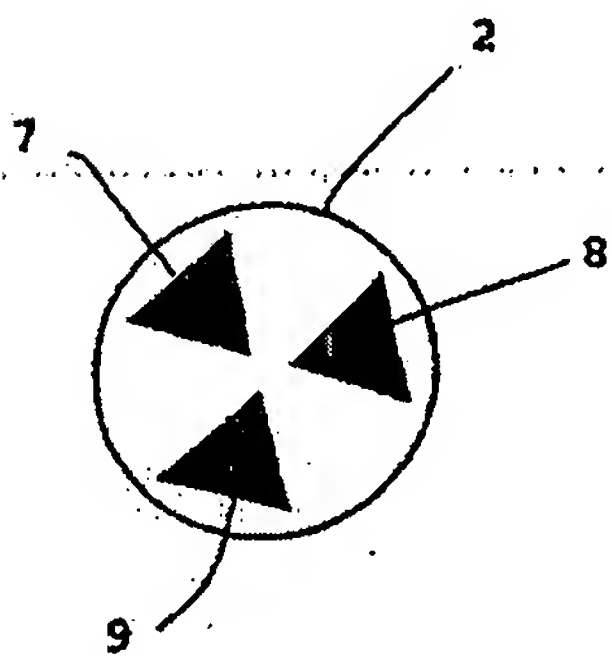


Fig. 4

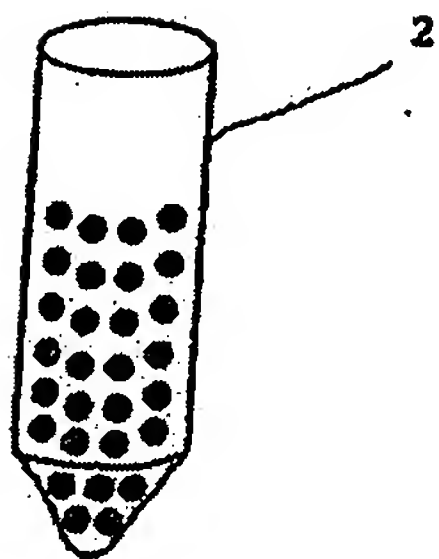
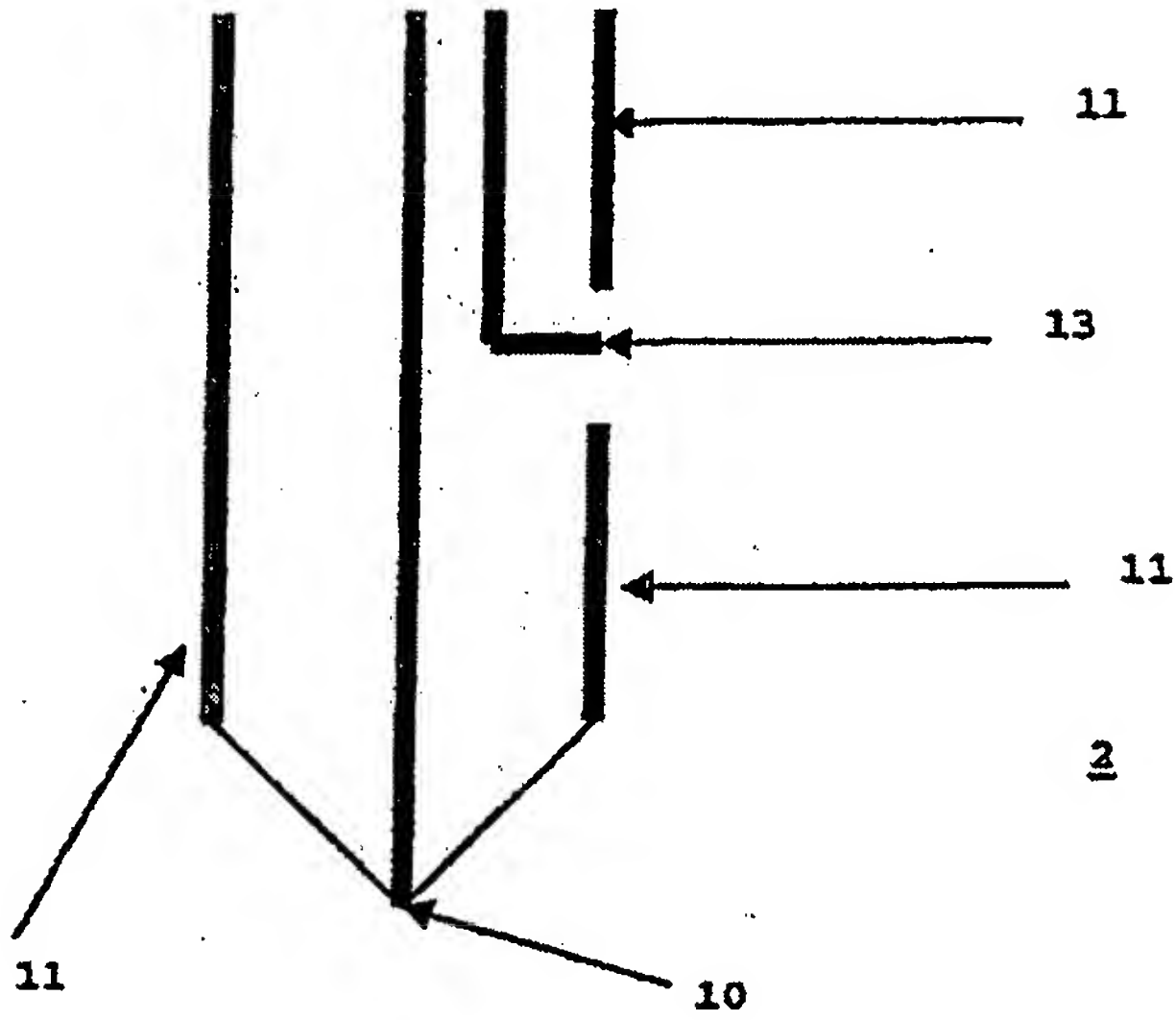


Fig. 5

DLA Piper Rudnick Gray Cary US LLP: (215) 656-3381



**Fig. 6**

**SUBSTITUTE SPECIFICATION (Clean Copy)**

**EXPLORATION DEVICE TO MONITOR THE PENETRATION  
OF AN INSTRUMENT IN AN ANATOMIC STRUCTURE**

**Related Application**

[0001] This is a §371 of International Application No. PCT/FR2005/000338, with an international filing date of February 11, 2005 (WO 2005/077282 A1, published August 25, 2005), which is based on French Patent Application No. 04/01361, filed February 11, 2004.

**Technical Field**

[0002] This invention refers to the field of spinal surgery.

**Background**

[0003] In surgery of the spine, for example, for pedicular drilling, the bone cortex is often crossed, broken or damaged by the drilling instrument, that may then lead to poor positioning of the pedicular screws. Following this poor positioning, the pedicular screws, inducing pain, paralysis, haemorrhage, etc. in the patient, may require another surgical intervention or, in certain cases, cause irreparable damage.

[0004] FR 2 835 732 discloses a device to monitor penetration of an instrument (drill or other type of instrument) in the vertebra by measuring the differences in the electrical impedance during penetration so that the practitioner is constantly aware whether the end of the instrument is leaving the bone cortex and penetrating into a zone of soft tissue (marrow, nerves, tissue). In that case, the practitioner modifies the path of the penetration instrument to return to the bone cortex.

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[0005] Such a device may also be used to detect the formation of a gap in the bone cortex during drilling.

[0006] To facilitate repositioning of the penetration instrument during a drilling operation (or similar type of operation such as tapping, boring, etc.), but also to enable proper positioning of the pedicular screw or any other surgical instrument, the practitioner has to know the exact position of the gaps formed during the drilling.

[0007] It could therefore be advantageous to provide an exploration device indicating the position of the gaps formed during a drilling (or similar) operation.

#### Summary

[0008] This invention relates to an exploration device to monitor the penetration of an instrument in an anatomic structure including at least two electrodes, a source of voltage supplying the at least two electrodes, a means for measuring impedance between the electrodes, a means of angular location formed by at least one electrode punctually coinciding with a peripheral surface of the penetration instrument, the coinciding surface of the electrode having a position set off from a longitudinal axis of the instrument, and means for detecting a position of the at least one electrode.

#### Brief Description of the Drawings

[0009] Selected, representative aspects will be better understood using the following description that is only provided for explanatory purposes, with reference to the appended figures:

Fig. 1 is a diagram of an exploration device;



Fig. 2 is a front cutaway view of the distal end of the penetration instrument according to one configuration;

Fig. 3 is a longitudinal cutaway view of the penetration instrument according to another configuration;

Fig. 4 is a front cutaway view of the distal end of the penetration instrument according to still another configuration;

Fig. 5 is a perspective view of the penetration instrument according to yet another configuration; and

Fig. 6 is a longitudinal cutaway view of the penetration instrument according to a further configuration.

#### Detailed Description

[0010] We disclose exploration devices to monitor penetration of an instrument in an anatomic structure, in particular bone structure, comprising a source of voltage supplying at least two electrodes and a means to measure the impedance between the electrodes. The device includes a means of angular location formed by at least one electrode punctually coinciding with a peripheral surface of the penetration instrument, the coinciding surface of the electrode whose position is set off from the longitudinal axis of the instrument, as well as a means to detect the position of the electrode.

[0011] By "punctual coincidence" and "punctually coinciding," we mean a contact surface partially and discontinually coinciding with the peripheral surface of the aforementioned penetration instrument. In particular, an angular contact surface, and by extension a tubular shape are not considered as providing punctual coincidence.

- [0012] Depending on whether one desires taking lateral readings or readings at the end of the penetration instrument or laterally and at the end, respectively, the penetration instrument may be equipped with at least one electrode coinciding with the lateral surface of the penetration instrument and/or at least one electrode coinciding with the peripheral surface of the distal end of the penetration instrument.
- [0013] Advantageously, the coinciding electrode is driven in rotation, the coinciding electrode being driven at speed of rotation so that it sweeps at least 360 degrees per level of insertion of the penetration instrument in the bone structure.
- [0014] The device may comprise a plurality of angularly spaced coinciding fixed electrodes and the means to measure the impedance delivers a signal corresponding to each of the electrodes.
- [0015] The electrodes may consist of punctual contacts longitudinally and angularly spaced out.
- [0016] The electrodes may be formed by longitudinal strips.
- [0017] According to one selected configuration, the electrodes are distributed around the longitudinal axis of the penetration instrument.
- [0018] The electrodes may be symmetrically arranged with respect to the longitudinal axis of the penetration instrument.
- [0019] The electrodes may consist of conducting rods of circular, semi-annular, rectangular and/or triangular section. In addition, they may consist of eccentric conducting rods.
- [0020] According to the realm of intervention in which the penetration instrument is used, the device may comprise at least one electrode at its distal end(s). The device may also comprise

two electrodes arranged at the distal end of the penetration instrument, the electrodes consisting of conducting rods of concentric circular section.

[0021] The means of detection may consist of visual marking preferably on the handle of the exploration device. According to one specific means of creation of the device, the handle forms the means of detection.

[0022] The device may also comprise a central channel for the passage of an additional instrument.

[0023] Turning now to the Drawings, the exploration device (1), illustrated in Fig. 1, is a device enabling the monitoring of the penetration of an instrument (2) in the bone structures of a human or animal body, the structures having at least two different zones of electrical impedance.

[0024] The exploration device (1) comprises a source of voltage (not shown) supplying at least two electrodes and a means to measure the impedance between the electrodes.

[0025] At least one of the electrodes is found on the penetration instrument (2).

[0026] The device also comprises means for signalling producing a signal at the time of detection, by impedometer, a variation of impedance, and therefore the presence of a gap. The means for signalling includes emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator, etc.).

[0027] The device may also comprise means for the acquisition and visualisation of the position of the gaps during penetration of the instrument (2) in the bone structure.

[0028] According to the applications considered, the penetration instrument (2) may either be fixed, or manually driven in rotation by means of drive of the motor type (not shown).

[0029] Therefore, it may include in one configuration, for example, of a probe, a square tip, a spatula, a curette or other, and in a second configuration, for example, of a screw, a drill, a tap, or other.

[0030] In the following section, the penetration instrument (2) includes a probe (2). However, the configurations presented are of course applicable to other penetration instruments mentioned above.

[0031] Fig. 2 illustrates one configuration of the probe (2) forming the exploration device (1).

[0032] In this configuration, the penetration instrument (2) has two eccentric electrodes (3, 4) of circular section at its distal end, electrode (3) being surrounded but separated from electrode (4) by an insulation ring (5).

[0033] In this example, electrode (3) comprises the positive pole of the electronic device, the negative pole of the electronic device comprising the electrode (4). This is only one example of an electronic device whose positive pole includes the electrode (4) and the negative pole of the electrode (3). Variations are within the skill in the art.

[0034] Each electrode (3, 4) is arranged to coincide with the surface of the penetration instrument (2).

[0035] To avoid any disturbance of the signal, the surface of the central or internal electrode (3) coinciding with the surface of the penetration instrument (2) remains relatively small with respect to the dimensions of the hole made in the bone cortex during the drilling (or other) operation.

[0036] The position of the electrode (3) is detected by specific marking on the exploration device (1). Advantageously, the marking is carried out by means of the handle (6) of the

exploration device (1). It may, for example, include a visual signal, for example, an arrow, represented on the handle (6). The marking may also include any means directly on the handle (6), such as, for example, a specific shape of the handle (6).

[0037] Therefore, during penetration of the instrument (2) in the perforated bone structure, a signal is given off by the means for signalling when a variation in impedance measured between the electrodes (3, 4) is detected by the impedometer, indicating the presence of a gap.

[0038] Following such detection, the means for signalling emit a warning signal (visual, sound or tactile). The practitioner then knows that the electrode (3) from the penetration instrument is positioned in front of a gap.

[0039] The practitioner then determines the direction of the gap with the mark corresponding to the position of the electrode (3) marked on the handle (6) of the exploration device (1).

[0040] In order to enable full scanning of the bone structure, the penetration instrument (2) is endowed with a movement of rotation, the speed of rotation exceeding the speed of progress of the penetration instrument (2) in the bone structure. In other words, the speed of rotation of the instrument (2) is such that the aforementioned penetration instrument (2) sweeps at least 360 degrees by level of penetration.

[0041] Fig. 3 illustrates another configuration of the probe (2) comprising the exploration device (1), which enables detection of gaps laterally arranged with respect to the body of the penetration instrument (2).

[0042] In this configuration, the electrode (3) is positioned in the penetration instrument (2) to punctually coincide with the lateral surface of the penetration instrument (2).

[0043] As for the electrode (4), it is distributed on the rest of the lateral surface of the penetration instrument (2), including its distal end. The electrodes (3, 4) are separated from each other by an insulant (5).

[0044] The principle of detection and the determination of the direction of the gap are identical to that described above.

[0045] Fig. 4 illustrates another configuration of the probe (2) comprising the exploration device (1), which enables detection of gaps arranged at the end of the penetration instrument (2).

[0046] In this configuration, the penetration instrument (2) has three electrodes (7, 8, 9) of sensibly identical triangular section at the distal end. The electrodes (7, 8, 9) distributed around the longitudinal axis of the penetration instrument (2) are angularly spaced. Advantageously, the angular space is identical.

[0047] Since the position of the electrodes (7, 8, 9) is known by the construction, their arrangement on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes for which a signal is emitted.

[0048] Since the number and triangular shape of the electrodes is given here by way of example, it is understood that the penetration instrument (2) may have a greater number of electrodes and a shape other than triangular. The determination of the direction of the gaps is all the more exact when the number of electrodes distributed at the end of the instrument (2) is higher.

[0049] Fig. 5 illustrates another configuration of the probe (2), enabling detection of the gaps arranged at the end of the penetration instrument (2), but also laterally.



[0050] In this configuration, the penetration instrument (2) includes a plurality of electrodes coinciding with the lateral surface of the penetration instrument (2) and at the distal end of the penetration instrument (2).

[0051] Since the position of each electrode is known, it is then possible to determine the position of the gap by the emission of a signal by the impedometer corresponding to the electrode positioned in front of the gap.

[0052] In the configurations presented above, the means to determine the position of the gaps include fixed electrodes. According to yet another configuration of the penetration instrument (2) (not shown), the gaps may also be determined by means of one or several mobile electrodes.

[0053] In addition, in the previous examples, the electrodes (3, 4) are respectively carried by the penetration instrument (2). Of course, the penetration instrument (2) may be equipped with only one electrode (3), the other electrode being positioned on the patient, and more specifically, on a surface other than the surgical wound, without going beyond the field of the invention.

[0054] As specified above, the configurations presented remain applicable to the other penetration instruments mentioned above.

[0055] In particular, in the case where the penetration instrument (2) includes a drill element, the penetration instrument (2) may advantageously comprise at least one electrode (13) coinciding with the lateral surface of the penetration instrument (2), as well as two electrodes (10, 11) concentrically arranged at the distal end of the penetration instrument (2) (Fig. 6). It is therefore possible, due to the configuration of the penetration instrument (2) to determine the presence and direction of a gap by means of electrodes (11 and 13), as well as prevent any possible perforation of the bone cortex using electrodes (10 and 11). For this purpose, the positioning of a lateral electrode consisting of a rod extending to the distal end should be

avoided. In fact, it would likely be impossible with such a configuration to know whether the zone detected by the electrodes is lateral or distal.

[0056] This disclosure is described above by way of example. It is understood that one skilled in the art is able to create different variations of the structures described and/or shown without departing from the subject matter recited in the appended claims.

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# **EXHIBIT D**

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19 septembre 2007

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Nos réf PASRV/757056.1  
Dossier réf W1210/00158

Monsieur Gérard Vanacker  
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**Lettre recommandée avec  
accusé de réception**

**DEPOT DE LA DEMANDE INTERNATIONALE  
PCT/FR2005/00338 AUX ETATS-UNIS**

Monsieur,

Nous sommes les conseils de la société SpineVision SA.

Dans le cadre de l'enregistrement de la demande américaine n° 10/589,182 déposée le 11 août 2006 (35904/PCT/US) et correspondant à la demande internationale PCT/FR2005/00338 ayant pour titre "Exploration device to monitor the penetration of an instrument in an anatomic structure" concernant une invention pour laquelle vous êtes l'un des inventeurs désignés, notre client nous a demandé de vous transmettre les documents suivants :

- un exemplaire corrigé de "Combined Declaration, Power of Attorney and Petition",
- un exemplaire corrigé de "Assignment",
- un exemplaire du fascicule de publication de la demande PCT FR2005/00338,
- un exemplaire du texte de la demande telle que déposée aux Etats-Unis,
- un exemplaire du texte américain remanié.

Nous vous remercions d'en prendre connaissance et de nous retourner le document intitulé "Combined Declaration, Power of Attorney and Petition" ainsi que le document "Assignment" chacun signé de votre main.

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Ces documents sont en effet indispensables à notre cliente dans le cadre de la délivrance du brevet américain correspondant à la demande internationale en cause.

Nous vous remercions de votre diligence et vous informons, conformément à nos règles déontologiques, que nous transmettons copie de la présente à votre conseil, notre Confrère Guillaume Teissonnière.

Nous vous prions de croire, Monsieur, en l'expression de notre considération distinguée.



Dominique Ménard  
Avocat à la Cour

P.J.

- ☐ Original Application  
☒ PCT National Application  
U.S. Designated Office  
☐ Continuation or Divisional Application  
☐ Continuation-in-Part Application

**COMBINED DECLARATION,  
POWER OF ATTORNEY AND PETITION**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **EXPLORATION DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE**

☐ which is described in the specification and claims

☐ attached hereto.

☐ filed on \_\_\_\_\_

Application Serial No. \_\_\_\_\_

and was amended on \_\_\_\_\_  
(if applicable)

☒ which is described in International Application No. PCT/FR2005/000338 filed February 11, 2005 and as amended on \_\_\_\_\_  
(if any).

which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION  
(Page 2)

Attorney Docket No. BDM-06-1208

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International Application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application(s) for patent or inventor's certificate or of any PCT International Application having a filing date before that of the application on which priority is claimed:

Number	Country	Date of Filing (day,month,year)	Priority Claimed
FR 04/01361	France	11 February 2004	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
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I hereby claim the benefit under Title 35, United States Code, §119(e) or §120 (as applicable) of any United States application(s) or §365(c) of any PCT International Application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International Application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112:

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(Application Serial No.)

\_\_\_\_\_  
(Filing Date)

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(Status)(patented,pending,abandoned)

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(Filing Date)

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(Status)(patented,pending,abandoned)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered attorneys to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith:

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**COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION**  
(Page 3)

Attorney Docket No. BDM-06-1208

I hereby petition for grant of a United States Letters Patent on this invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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7. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY		INVENTOR'S SIGNATURE		DATE
RESIDENCE		CITIZENSHIP		
POST OFFICE ADDRESS				

ASSIGNMENT

WHEREAS, we, Maurice Bourlion, Dominique Petit and Gérard Vanacker, citizens of France, residing at 9, rue Jean Vincent, F-42400 Saint-Chamond, France, 2, rue des Peupliers, F-62180 Verton, France and Villa Saint-Antoine, Rue du Sautiquet, F-83380 Les Issambres, France, respectively, (hereinafter referred to as "the undersigned"), having made an invention entitled EXPLORATION DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE, for which on the date set forth below, unless otherwise indicated here, \_\_\_\_\_, the undersigned executed an application for United States Letters Patent,

WHEREAS, Spinevision, a corporation of France, with offices at 180, avenue Daumesnil, F-75012 Paris, France (hereinafter referred to as "assignee"), is desirous of acquiring the entire right, title and interest in said invention, said application and all letters patent issuing for said invention,

NOW, THEREFORE, in consideration of One Dollar (\$1.00) and of other good and valuable consideration, receipt of which is hereby acknowledged, the undersigned, intending to be legally bound, does hereby sell, assign and transfer to the assignee the entire right, title and interest, for the United States of America, its territories and possessions, and for all foreign countries, in said invention, including said patent application, all divisions and continuations thereof, all rights to claim priority based thereon, all rights to file foreign applications on said invention, and all letters patent and reissues thereof, issuing for said invention in the United States of America and in any and all foreign countries.

It is agreed that the undersigned shall be legally bound, upon request of the assignee, or its successors or assigns or a legal representative thereof, to supply all information and evidence of which the undersigned has knowledge or possession, relating to the making and practice of said invention, to testify in any legal proceeding relating thereto, to execute all instruments proper to patent the invention in the United States of America and foreign countries in the name of the assignee, and to execute all instruments proper to carry out the intent of this instrument. If the undersigned includes more than one individual, these obligations shall apply to all of the undersigned both individually and collectively.

The rights and property herein conveyed by the undersigned are free and clear of any encumbrance.

EXECUTED on \_\_\_\_\_, 20\_\_\_\_, at \_\_\_\_\_.

\_\_\_\_\_  
Maurice Bourlion

\_\_\_\_\_  
Dominique Petit

\_\_\_\_\_  
Gérard Vanacker

\_\_\_\_\_  
Witness



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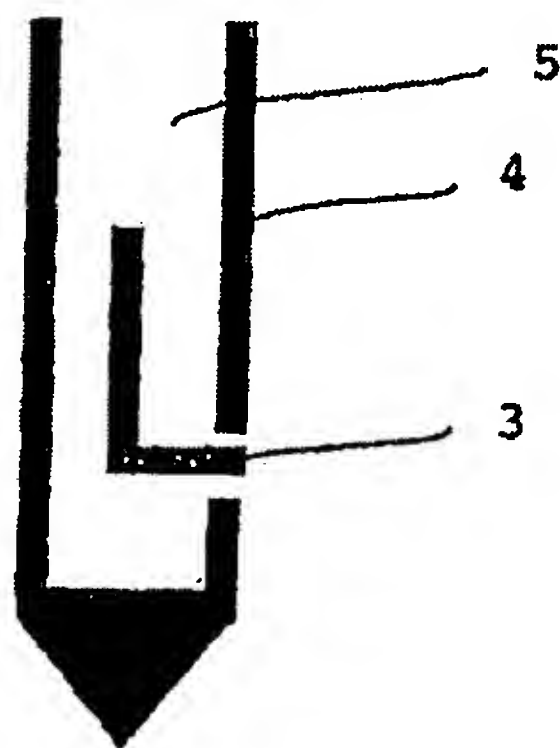
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(54) Title: EXPLORATION DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE

(54) Titre : DISPOSITIF D'EXPLORATION POUR LE SUIVI DE LA PÉNÉTRATION D'UN INSTRUMENT DANS UNE STRUCTURE ANATOMIQUE



(57) Abstract: The invention relates to an exploration device (1) for monitoring the penetration of an instrument (2) into an anatomical structure, particularly a bone structure. The inventive device comprises a voltage source which powers at least two electrodes (3, 4) and a means for measuring the impedance between said electrodes (3, 4). The invention is characterised in that the device (1) is equipped with an angular locating means comprising at least one electrode (3) which comes to the surface at a point on a peripheral surface of the penetrating instrument (2), the position of said electrode (3) being offset in relation to the longitudinal axis of the instrument.

(57) Abrégé : La présente invention se rapporte à un dispositif d'exploration (1) pour le suivi de la pénétration d'un instrument (2) dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes (3, 4) et un moyen de mesure de l'impédance entre lesdites électrodes (3, 4), caractérisé en ce que ledit dispositif (1) comporte un moyen de localisation angulaire constitué par au moins une électrode (3) affleurant ponctuellement une surface périphérique dudit instrument de pénétration (2), ladite électrode (3) présentant une position décalée par rapport à l'axe longitudinal dudit instrument.

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DISPOSITIF D'EXPLORATION POUR LE SUIVI DE LA PÉNÉTRATION  
D'UN INSTRUMENT DANS UNE STRUCTURE ANATOMIQUE

La présente invention se rapporte au domaine de la  
5 chirurgie rachidienne.

En chirurgie du rachis, par exemple lors du forage  
pédiculaire, il est fréquent que le cortex osseux soit  
traversé, cassé ou ébréché par l'instrument de forage,  
10 pouvant alors engendrer un mauvais positionnement des vis  
pédiculaires. Suivant ce mauvais positionnement, les vis  
pédiculaires, provoquent chez le patient des douleurs,  
paralysies, hémorragies, etc., nécessitant une nouvelle  
intervention chirurgicale, voire dans certains cas causant  
15 des dommages irréparables.

On connaît de la demande de brevet FR2835732, déposée  
par le présent demandeur, un dispositif permettant de  
suivre la pénétration d'un instrument (instrument de forage  
20 ou autre) dans la vertèbre par la mesure des différences  
d'impédance électrique au fur et à mesure de la  
pénétration, de sorte que le praticien sait, à chaque  
instant, si l'extrémité de l'instrument sort du cortex  
osseux et pénètre dans une zone de tissus mous (moelle,  
25 nerfs, tissus). Dans ce cas, le praticien modifie la  
trajectoire de l'instrument de pénétration pour revenir  
dans le cortex osseux.

Un tel dispositif permet ainsi de détecter la  
formation d'une brèche dans le cortex osseux au moment du  
30 forage.

Afin de faciliter le repositionnement de l'instrument  
de pénétration dans le cas d'une opération de forage (ou  
similaire, du type taraudage, perçage, ...), mais également  
de permettre un positionnement correct des vis pédiculaires  
35 ou de tout autre instrument chirurgical, il s'avère

nécessaire pour le praticien de connaître la position exacte des brèches formées au cours du forage.

La présente invention a donc pour objet de proposer  
5 un dispositif d'exploration permettant d'indiquer la position des brèches formées au cours d'une opération de forage (ou similaire).

À cet effet, l'invention concerne dans son  
10 acceptation la plus générale un dispositif d'exploration pour le suivi de la pénétration d'un instrument dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes et un moyen de mesure de l'impédance entre  
15 lesdites électrodes, et elle est remarquable en ce que ledit dispositif comporte un moyen de localisation angulaire constitué par au moins une électrode affleurant ponctuellement une surface périphérique dudit instrument de pénétration, la surface affleurante de ladite électrode (3)  
20 ayant une position décalée par rapport à l'axe longitudinal dudit instrument, ainsi qu'un moyen de repérage de la position de ladite au moins électrode (3).

Par affleurement ponctuel, on entend une surface de contact affleurant de manière partielle et discontinue la  
25 surface périphérique dudit instrument de pénétration. Ne constitue donc notamment pas un affleurement ponctuel, une surface de contact de forme annulaire, et par extension de forme tubulaire.

Selon que l'on souhaite effectuer des mesures  
30 latéralement ou en bout de l'instrument de pénétration ou respectivement latéralement et en bout, l'instrument de pénétration sera équipé d'une au moins électrode affleurant la surface latérale dudit instrument de pénétration et/ou d'une au moins électrodes affleurant la surface

périphérique de l'extrémité distale dudit instrument de pénétration.

Avantageusement, ladite électrode affleurante est entraînée en rotation, ladite électrode affleurante étant  
5 entraînée à une vitesse de rotation telle qu'elle balaye au moins 360 degrés par tranche d'enfoncement dudit instrument de pénétration dans la structure osseuse.

De préférence, ledit dispositif comporte une pluralité d'électrodes affleurantes fixes espacées  
10 angulairement et en ce que le moyen de mesure d'impédance délivre un signal correspondant à chacune desdites électrodes.

Avantageusement, lesdites électrodes consistent en des contacts ponctuels espacés longitudinalement et  
15 angulairement.

Avantageusement, lesdites électrodes sont formées de bandes longitudinales.

Selon une configuration particulière de l'invention, les électrodes sont réparties autour de l'axe longitudinal  
20 de l'instrument de pénétration.

Avantageusement, les électrodes sont disposées symétriquement par rapport à l'axe longitudinal dudit instrument de pénétration.

Avantageusement, lesdites électrodes sont constituées  
25 par des tiges conductrices de section circulaire, semi-annulaire, rectangulaire et/ou triangulaire. De même, elles peuvent être constituées par des tiges conductrices excentrées.

Selon le domaine d'intervention dans lequel est  
30 utilisé l'instrument de pénétration, ledit dispositif pourra comporter à son(ses) extrémité(s) distale(s) au moins une électrode. Avantageusement, ledit dispositif comporte deux électrodes disposées à l'extrémité distale dudit instrument de pénétration, lesdites électrodes étant

constitués par des tiges conductrices de section circulaire concentrique.

Avantageusement, ledit moyen de repérage consiste en un marquage visuel porté de préférence sur la poignée dudit  
5 dispositif d'exploration. Selon un mode de réalisation particulier de l'invention, ladite poignée (6) constitue ledit moyen de repérage.

Avantageusement, ledit dispositif comporte en outre un canal central pour le passage d'un instrument  
10 additionnel.

On comprendra mieux l'invention à l'aide de la description, faite ci-après à titre purement explicatif, en référence aux figures annexées :

- 15 - la figure 1 illustre une vue schématisée d'un dispositif d'exploration selon l'invention ;
- la figure 2 illustre une vue en coupe frontale de l'extrémité distale de l'instrument de pénétration selon une première configuration de l'invention ;
- 20 - la figure 3 illustre une vue en coupe longitudinale de l'instrument de pénétration selon une deuxième configuration de l'invention ;
- la figure 4 illustre une vue en coupe frontale de l'extrémité distale de l'instrument de pénétration selon  
25 une troisième configuration de l'invention ;
- la figure 5 illustre une vue en perspective de l'instrument de pénétration selon une quatrième configuration de l'invention ; et
- la figure 6 illustre une vue en coupe  
30 longitudinale de l'instrument de pénétration selon une cinquième configuration de l'invention.

Le dispositif d'exploration (1) selon l'invention, illustré figure 1, est un dispositif permettant le suivi de  
35 la pénétration d'un instrument (2) dans les structures



osseuses d'un corps humain ou animal, lesdites structures présentant au moins deux zones d'impédance électrique différentes.

Le dispositif d'exploration (1) comporte une source  
5 de tension (non représentée) alimentant au moins deux électrodes et un moyen de mesure de l'impédance (non représenté) entre lesdites électrodes.

L'une au moins desdites électrodes est disposée sur ledit instrument de pénétration (2).

10 Ledit dispositif comporte en outre des moyens de signalisation produisant un signal lors de la détection, par l'impédancemètre, d'une variation d'impédance, et donc de la présence d'une brèche. Lesdits moyens de signalisation consistent à l'émission d'un signal visuel,  
15 tel qu'un témoin lumineux, d'un signal sonore, et/ou d'un signal tactile (vibreur, ...).

Selon un mode avantageux de réalisation de l'invention, ledit dispositif comporte également des moyens d'acquisition et de visualisation de la position des  
20 brèches au cours de la pénétration de l'instrument (2) dans la structure osseuse.

Selon les applications envisagées, l'instrument de pénétration (2) peut être soit fixe, soit entraîné en  
25 rotation manuellement ou par des moyens d'entraînement du type moteur (non représentés).

Ainsi, il pourra s'agir, dans la première configuration, par exemple d'une sonde, d'une pointe carrée, d'une spatule, d'une curette ou autre, et dans la  
30 seconde configuration, par exemple d'une vis, d'une mèche de forage, de taraudage, ou autre.

Dans la partie ci-après, l'instrument de pénétration (2) consiste en une sonde (2). Cependant les configurations présentées sont bien entendu applicables aux autres  
35 instruments de pénétration mentionnés ci-dessus.

La figure 2 illustre une première configuration de la sonde (2) constituant ledit dispositif d'exploration (1).

Dans cette première configuration, l'instrument de pénétration (2) présente au niveau de son extrémité distale, deux électrodes (3, 4) de section circulaire et excentrique, l'électrode (3) étant entourée mais séparée de l'électrode (4) par une couronne d'isolant (5).

L'électrode (3) constitue, dans cet exemple de réalisation, le pôle positif dudit dispositif électronique, le pôle négatif dudit dispositif électronique étant constitué par l'électrode (4). Il est bien entendu évident qu'il ne s'agit ici que d'un exemple de réalisation, et que l'homme du métier pourra réaliser un dispositif électronique dont le pôle positif sera constitué par l'électrode (4) et le pôle négatif par l'électrode (3) sans pour autant sortir de l'invention.

Chaque électrode (3, 4) est disposée de sorte à affleurer la surface dudit instrument de pénétration (2).

Afin d'éviter toute perturbation du signal, la surface de l'électrode centrale ou interne (3) affleurant la surface dudit instrument de pénétration (2) reste relativement petite par rapport aux dimensions du trou effectué dans le cortex osseux lors de l'opération de forage (ou autre).

La position de l'électrode (3) est repérée par un marquage spécifique sur ledit dispositif d'exploration (1). Avantageusement, le marquage est effectué au moyen de la poignée (6) dudit dispositif d'exploration (1). Il pourra s'agir par exemple d'une signalisation visuelle, comme par exemple une flèche, représentée sur la poignée (6). Le marquage pourra être réalisé également au moyen directement de la poignée (6), comme par exemple une forme spécifique de ladite la poignée (6).



Ainsi, lors de la pénétration de l'instrument (2) dans la structure osseuse perforée, un signal est émis par lesdits moyens de signalisation lorsque une variation d'impédance mesurée entre les électrodes (3, 4) est  
5 détectée par l'impédancemètre, indiquant la présence d'une brèche.

Suite à cette détection, les moyens de signalisation émettent un signal d'alerte (visuel, sonore, ou tactile). Le praticien sait à ce moment que l'électrode (3) de  
10 l'instrument de pénétration est positionnée devant une brèche.

Le praticien détermine alors la direction de la brèche grâce au repère correspondant au positionnement de l'électrode (3) marqué sur la poignée (6) dudit dispositif  
15 d'exploration (1).

Afin de permettre un balayage complet de la structure osseuse, ledit instrument (2) de pénétration est animé d'un mouvement de rotation, la vitesse de rotation étant supérieure à la vitesse d'avancement de l'instrument (2) de  
20 pénétration dans la structure osseuse. En d'autres termes, la vitesse de rotation dudit instrument (2) sera telle que ledit instrument (2) de pénétration balayera au moins 360 degrés par tranche d'enfoncement.

25 La figure 3 illustre une seconde configuration de la sonde (2) constituant ledit dispositif d'exploration (1), laquelle permet de détecter des brèches disposées latéralement par rapport au corps dudit instrument (2) de pénétration.

30 Dans cette seconde configuration, l'électrode (3) est positionnée dans ledit instrument de pénétration (2) de sorte à affleurer ponctuellement la surface latérale dudit instrument (2) de pénétration.

L'électrode (4), quant à elle, est répartie sur le  
35 reste de la surface latérale restante dudit instrument (2)

de pénétration, y compris son extrémité distale. Lesdites électrodes (3, 4) sont séparées l'une de l'autre par un isolant (5).

Le principe de détection et de détermination de la direction de la brèche est identique à celui exposé précédemment.

La figure 4 illustre une troisième configuration de la sonde (2) constituant ledit dispositif d'exploration (1), laquelle permet de détecter des brèches disposées à l'extrémité dudit instrument (2) de pénétration.

Dans cette troisième configuration, l'instrument de pénétration (2) présente au niveau de son extrémité distale trois électrodes (7, 8, 9) de section triangulaire sensiblement identiques. Lesdites électrodes (7, 8, 9), réparties autour de l'axe longitudinalement de l'instrument (2) de pénétration, sont espacées angulairement. Avantageusement, l'espacement angulaire est identique.

La position des électrodes (7, 8, 9) étant connue par construction, leur disposition sur l'extrémité distale donne des indications sur la position des brèches. En effet, la brèche détectée sera située entre les deux électrodes pour lesquelles un signal est émis.

Le nombre et la forme triangulaire des électrodes étant donné ici à titre d'exemple, il est entendu que ledit instrument (2) de pénétration peut présenter des électrodes en nombre supérieur et de forme autre que triangulaire. La détermination de la direction des brèches sera d'autant plus précise que le nombre d'électrodes réparties à l'extrémité dudit instrument (2) sera élevé.

La figure 5 illustre une autre configuration de la sonde (2), permettant de détecter des brèches disposées à l'extrémité dudit instrument (2) de pénétration, mais également latéralement.

Dans cette configuration, ledit instrument (2) de pénétration est constitué d'une pluralité d'électrodes disposées affleurantes à la surface latérale dudit instrument (2) de pénétration et à l'extrémité distale dudit instrument (2).

La position de chaque électrode étant connue, il est alors possible, comme pour la troisième configuration, de déterminer la position de la brèche par l'émission d'un signal par l'impédancemètre correspondant à l'électrode positionnée face à la brèche.

Dans les configurations précédemment présentées, les moyens de détermination de la position des brèches consistent en des électrodes fixes. Selon une configuration particulière de l'instrument (2) de pénétration (non représentée), la détermination des brèches pourra être également effectuée au moyen d'une ou plusieurs électrodes mobiles.

De même, dans les exemples précédents, les électrodes (3, 4) sont portées respectivement par ledit instrument de pénétration (2). Il va de soi que ledit instrument de pénétration (2) pourra être muni d'une seule électrode (3), l'autre électrode étant positionnée sur le patient, et plus particulièrement sur une surface autre que la plaie opératoire, sans pour autant sortir du champ de l'invention.

Comme cela a été précisé précédemment, les configurations présentées restent applicables aux autres instruments de pénétration mentionnés ci-dessus.

En particulier, dans le cas où l'instrument (2) de pénétration consiste en un élément de forage, ledit instrument (2) de pénétration pourra avantageusement comporter au moins une électrode (13) affleurant la surface

latérale dudit instrument (2) de pénétration, ainsi que deux électrodes (10, 11) disposées concentriquement à l'extrémité distale dudit instrument (2) de pénétration (figure 6). Il sera ainsi possible, de part la  
5 configuration dudit instrument (2) de pénétration de déterminer la présence et la direction d'une brèche au moyen des électrodes (11 et 13), ainsi que de prévenir une éventuelle perforation du cortex osseux au moyen des électrodes (10 et 11). A cet effet, il devra être évité de  
10 positionner une électrode latérale consistant en une tige allant jusqu'à l'extrémité distale. Il serait en effet impossible, avec une telle configuration, de savoir si la zone détectée par les électrodes est latérale ou distale.

15 L'invention est décrite dans ce qui précède à titre d'exemple. Il est entendu que l'homme du métier est à même de réaliser différentes variantes de l'invention sans pour autant sortir du cadre du brevet.

REVENDICATIONS

1. Dispositif d'exploration (1) pour le suivi de la pénétration d'un instrument (2) dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes (3, 4) et un moyen de mesure de l'impédance entre lesdites électrodes (3, 4), caractérisé en ce que ledit dispositif (1) comporte un moyen de localisation angulaire constitué par au moins une électrode (3) affleurant ponctuellement une surface périphérique dudit instrument de pénétration (2), la surface affleurante de ladite électrode (3) ayant une position décalée par rapport à l'axe longitudinal dudit instrument, ainsi qu'un moyen de repérage de la position de ladite au moins électrode (3).

2. Dispositif d'exploration (1) selon la revendication 1, caractérisé en ce que ladite électrode (3) affleure ponctuellement la surface latérale dudit instrument de pénétration (2).

3. Dispositif d'exploration (1) selon la revendication 1 ou la revendication 2, caractérisé en ce que ladite électrode (3) affleure ponctuellement la surface périphérique de l'extrémité distale dudit instrument de pénétration (2).

4. Dispositif d'exploration (1) selon l'une quelconque des revendications précédentes, caractérisé en ce que ladite électrode (3) affleurante est entraînée en rotation.

5. Dispositif d'exploration (1) selon la revendication précédente, caractérisé en ce que ladite électrode (3) affleurante est entraînée à une vitesse de



rotation telle que ladite électrode (3) balaye au moins 360 degrés par tranche d'enfoncement dudit instrument de pénétration (2) dans la structure osseuse.

5           6. Dispositif d'exploration (1) selon la revendication 1, caractérisé en ce qu'il comporte une pluralité d'électrodes (3, 4, 7, 8, 9) affleurantes fixes espacées angulairement et en ce que le moyen de mesure d'impédance délivre un signal correspondant à chacune  
10 desdites électrodes (3, 4, 7, 8, 9).

          7. Dispositif d'exploration (1) selon la revendication 6, caractérisé en ce que lesdites électrodes (3, 4, 7, 8, 9) consistent en des contacts ponctuels  
15 espacés longitudinalement et angulairement.

          8. Dispositif d'exploration (1) selon la revendication 6, caractérisé en ce que lesdites électrodes (3, 4, 7, 8, 9) sont formées de bandes longitudinales.  
20

          9. Dispositif d'exploration (1) selon l'une quelconque des revendications 6 à 8, caractérisé en ce que les électrodes (3, 4, 7, 8, 9) sont réparties autour de l'axe longitudinal de l'instrument de pénétration (2).  
25

          10. Dispositif d'exploration (1) selon l'une quelconque des revendications 6 à 9, caractérisé en ce que les électrodes (3, 4, 7, 8, 9) sont disposées symétriquement par rapport à l'axe longitudinal dudit  
30 instrument de pénétration (2).

          11. Dispositif d'exploration (1) selon l'une quelconque des revendications 6 à 10, caractérisé en ce que lesdites électrodes (3, 4, 7, 8, 9) sont constituées par



des tiges conductrices de section circulaire, semi-annulaire, rectangulaire et/ou triangulaire.

12. Dispositif d'exploration (1) selon l'une  
5 quelconque des revendications 6 à 11, caractérisé en ce que lesdites électrodes sont constituées par des tiges conductrices excentrées.

13. Dispositif d'exploration (1) selon l'une  
10 quelconque des revendications précédentes, caractérisé en ce que ledit dispositif comporte (1) en outre au moins une électrode disposée à l'extrémité distale dudit instrument de pénétration.

14. Dispositif d'exploration (1) selon la  
15 revendication précédente, caractérisé en ce que ledit dispositif (1) comporte deux électrodes disposées à l'extrémité distale dudit instrument de pénétration, lesdites électrodes étant constituées par des tiges  
20 conductrices de section circulaire concentrique.

15. Dispositif d'exploration (1) selon l'une  
quelconque des revendications précédentes, caractérisé en ce que ledit moyen de repérage consiste en un marquage  
25 visuel porté de préférence sur la poignée (6) dudit dispositif d'exploration (1).

16. Dispositif d'exploration (1) selon l'une  
quelconque des revendications précédentes, caractérisé en  
30 ce que le dispositif d'exploration (1) comporte une poignée (6) constituant ledit moyen de repérage.

17. Dispositif d'exploration (1) selon l'une  
quelconque des revendications précédentes, caractérisé en

ce qu'il comporte une poignée constituant ledit moyen de repérage.

18. Dispositif d'exploration (1) selon l'une  
5 quelconque des revendications précédentes, caractérisé en  
ce qu'il comporte un canal central pour le passage d'un  
instrument additionnel.

1/4

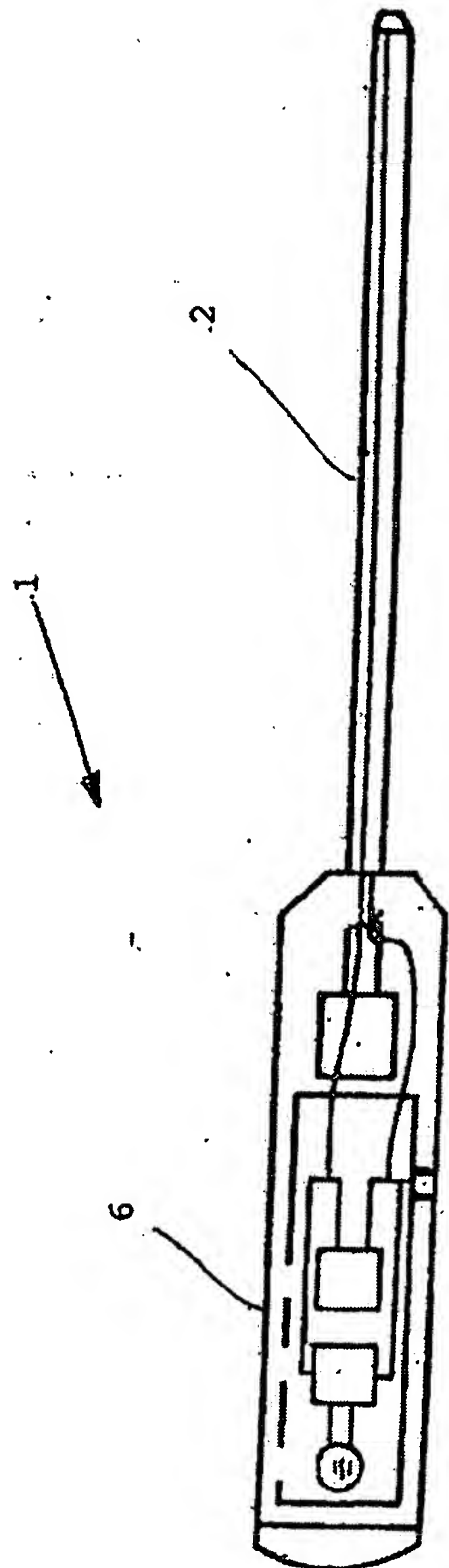


Fig. 1

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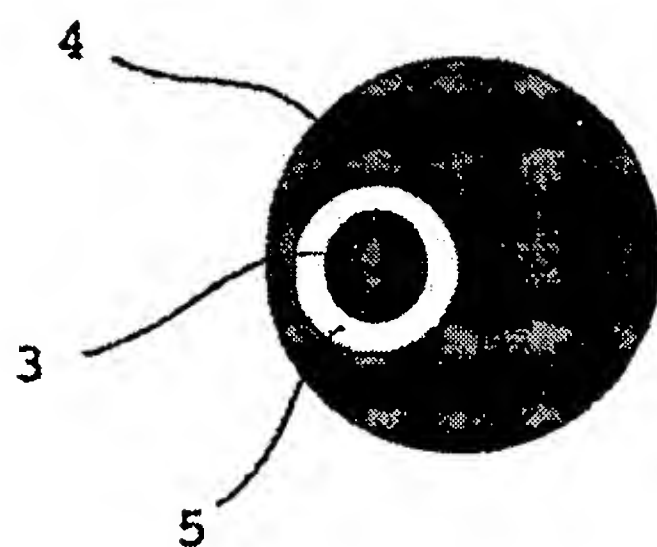


Fig. 2

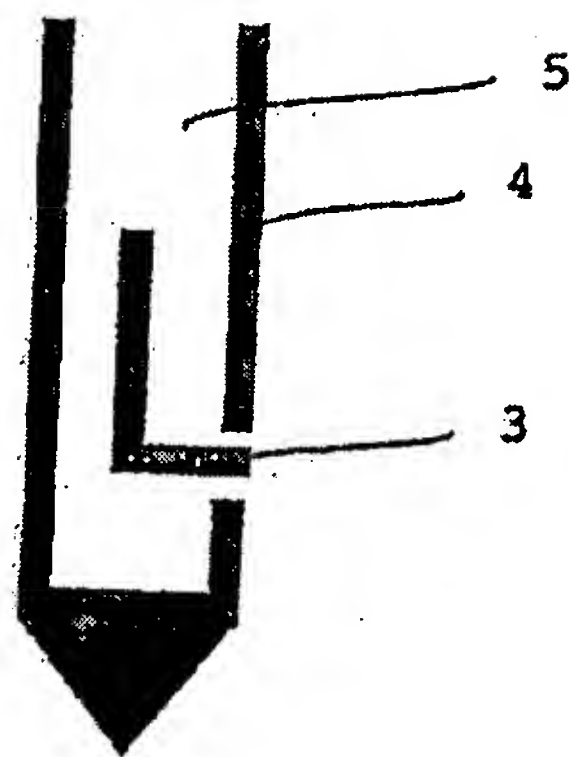


Fig. 3

3/4

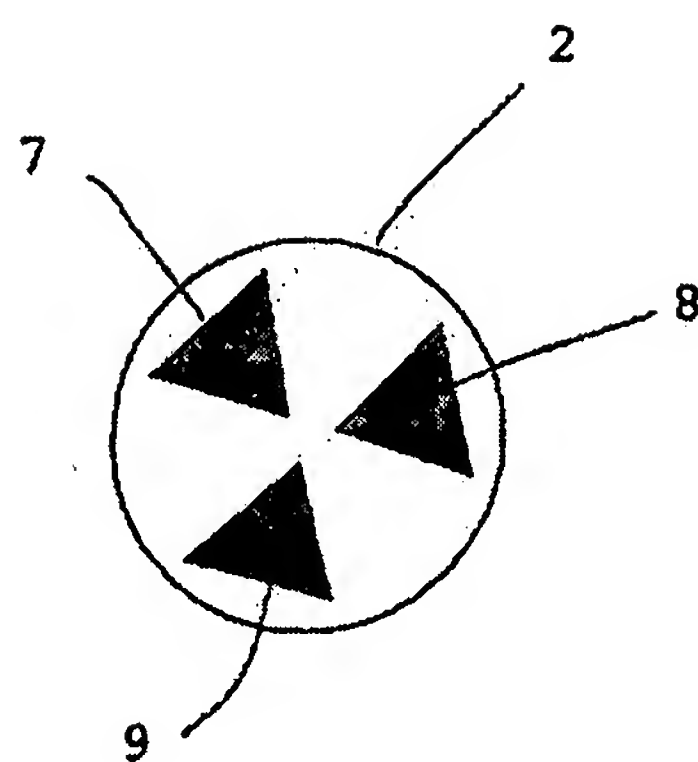


Fig. 4

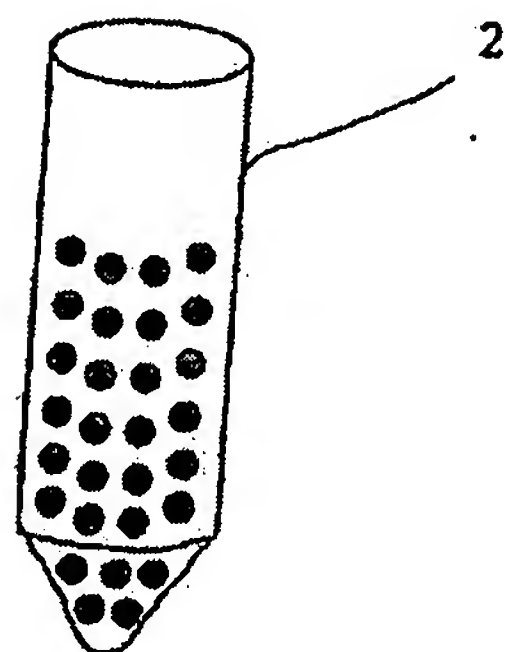


Fig. 5

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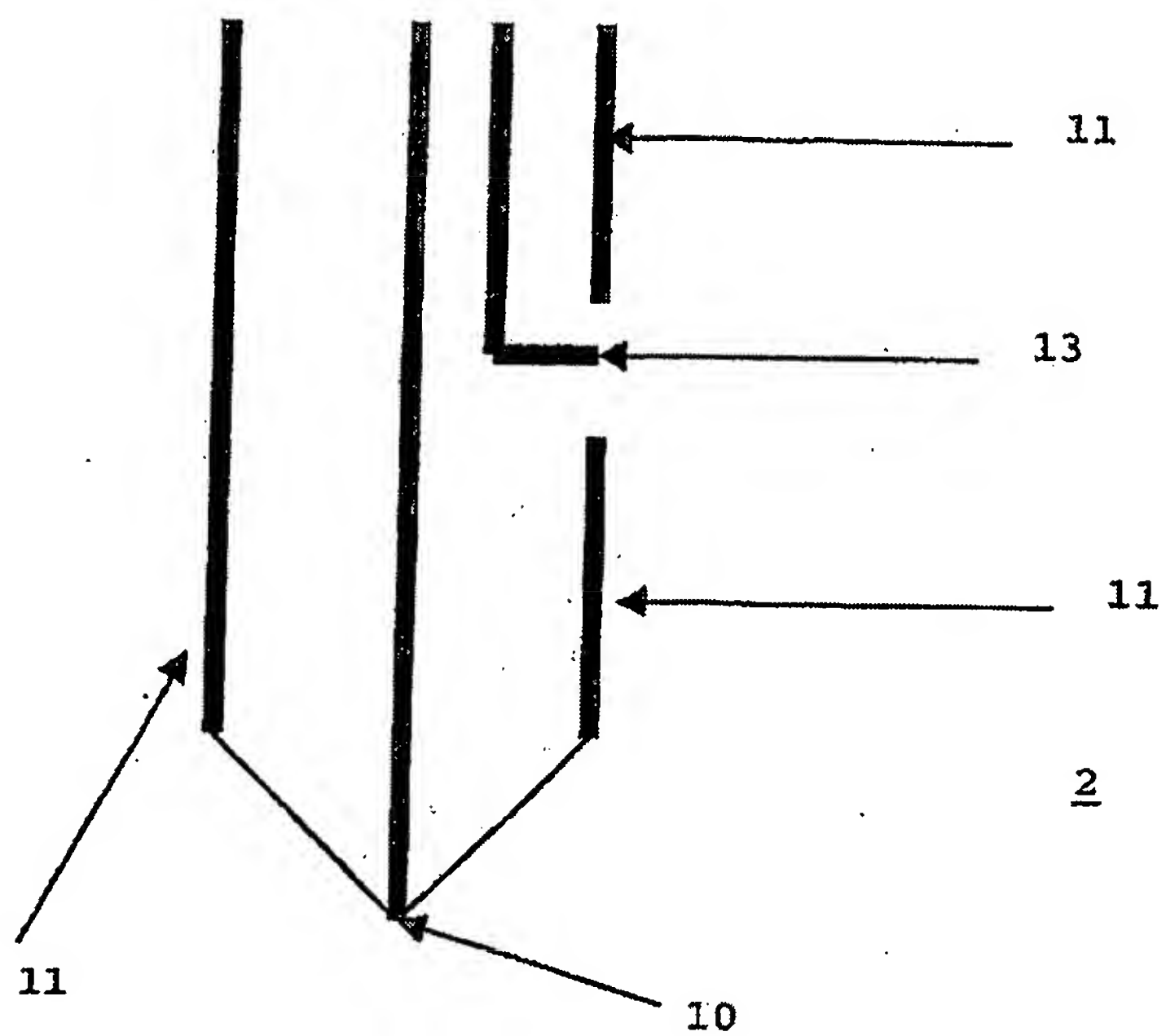


Fig. 6



# INTERNATIONAL SEARCH REPORT

International Application No

PCT/FR2005/000338

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B17/16

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61C A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 835 732 A (SPINEVISION) 15 August 2003 (2003-08-15) cited in the application page 4, line 11 - line 35 page 8, line 1 - line 3 page 8, line 26 - line 31 page 9, line 19 - line 22 page 9, line 34 - line 35 page 12, line 13 - line 23 claims 8,9; figures 1-7	1-18
X	US 6 391 005 B1 (LUM P. ET AL) 21 May 2002 (2002-05-21) column 1, line 62 - column 2, line 4 column 3, line 28 - line 49 column 6, line 46 - column 7, line 16 figures 1,2	1,4,13, 18

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Z" document member of the same patent family

Date of the actual completion of the international search

8 June 2005

Date of mailing of the international search report

20/06/2005

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/FR2005/000338

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
FR 2835732	A	15-08-2003	FR 2835732 A1	15-08-2003
			AU 2003216974 A1	04-09-2003
			EP 1474046 A1	10-11-2004
			WO 03068076 A1	21-08-2003
US 6391005	B1	21-05-2002	DE 19914485 A1	18-11-1999
			GB 2335990 A	06-10-1999
			JP 11309124 A	09-11-1999
			US 2002042594 A1	11-04-2002

# RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale No

PCT/FR2005/000338

A. CLASSEMENT DE L'OBJET DE LA DEMANDE  
CIB 7 A61B17/16

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)

CIB 7 A61B A61C A61N

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)

EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
X	FR 2 835 732 A (SPINEVISION) 15 août 2003 (2003-08-15) cité dans la demande page 4, ligne 11 - ligne 35 page 8, ligne 1 - ligne 3 page 8, ligne 26 - ligne 31 page 9, ligne 19 - ligne 22 page 9, ligne 34 - ligne 35 page 12, ligne 13 - ligne 23 revendications 8,9; figures 1-7	1-18
X	US 6 391 005 B1 (LUM P. ET AL) 21 mai 2002 (2002-05-21) colonne 1, ligne 62 - colonne 2, ligne 4 colonne 3, ligne 28 - ligne 49 colonne 6, ligne 46 - colonne 7, ligne 16 figures 1,2	1,4,13, 18

☐ Voir la suite du cadre C pour la fin de la liste des documents

☒ Les documents de familles de brevets sont indiqués en annexe

\* Catégories spéciales de documents cités:

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"Y" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du métier

"Z" document qui fait partie de la même famille de brevets

Date à laquelle la recherche internationale a été effectivement achevée

8 juin 2005

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Nom et adresse postale de l'administration chargée de la recherche internationale

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# RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Demande internationale No

PCT/FR2005/000338

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
FR 2835732	A	15-08-2003	FR 2835732 A1	15-08-2003
			AU 2003216974 A1	04-09-2003
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US 6391005	B1	21-05-2002	DE 19914485 A1	18-11-1999
			GB 2335990 A	06-10-1999
			JP 11309124 A	09-11-1999
			US 2002042594 A1	11-04-2002

EXPLORATION DEVICE TO MONITOR THE PENETRATION  
OF AN INSTRUMENT IN AN ANATOMIC STRUCTURE

- [0001] The present invention refers to the field of spinal surgery.
- [0002] In surgery of the spine, for example for pedicular drilling, the bone cortex is often crossed, broken or damaged by the drilling instrument, that may then lead to the poor positioning of the pedicular screws. Following this poor positioning, the pedicular screws, inducing pain, paralysis, haemorrhage, etc. in the patient, may require another surgical intervention or, in certain cases, cause irreparable damage.
- [0003] We are familiar with patent application FR2835732, filed by the present applicant, a device to monitor the penetration of an instrument (dill or other type of instrument) in the vertebra by measuring the differences in the electrical impedance during the penetration, so that the practitioner is constantly aware whether the end of the instrument is leaving the bone cortex and penetrating into a zone of soft tissue (marrow, nerves, tissue). In this case, the practitioner modifies the path of the penetration instrument in order to return to the bone cortex.
- [0004] Such a device may also be used to detect the formation of a gap in the bone cortex during drilling.
- [0005] To facilitate the repositioning of the penetration instrument during a drilling operation (or similar type of operation such as tapping, boring, etc.), but also to enable the proper positioning of the pedicular screw or any other surgical instrument, the practitioner has to know the exact position of the gaps formed during the drilling.
- [0006] The present invention therefore aims at proposing an exploration device indicating the position of the gaps formed during a drilling (or similar) operation.



[0007] For this purpose, the invention involves, according to its most general acceptance, an exploration device to monitor the penetration of an instrument in an anatomic structure, in particular bone structure, comprising a source of voltage supplying at least two electrodes and a means to measure the impedance between the aforementioned electrodes, and is it remarkable in that the aforementioned device includes a means of angular location formed by at least one electrode punctually coinciding with a peripheral surface of the aforementioned penetration instrument, the coinciding surface of the aforementioned electrode (3) whose position is set off from the longitudinal axis of the aforementioned instrument, as well as a means to detect the position of the aforementioned electrode (3).

[0008] By punctual coincidence, we mean a contact surface partially and discontinually coinciding with the peripheral surface of the aforementioned penetration instrument. In particular, an angular contact surface, and by extension a tubular shape are not considered as providing punctual coincidence.

[0009] Depending on whether one desires taking lateral readings or readings at the end of the penetration instrument or laterally and at the end, respectively, the penetration instrument will be equipped with at least one electrode coinciding with the lateral surface of the aforementioned penetration instrument and/or at least one electrode coinciding with the peripheral surface of the distal end of the aforementioned penetration instrument.

[0010] Advantageously, the aforementioned coinciding electrode is driven in rotation, the aforementioned coinciding electrode being driven at speed of rotation so that it sweeps at least 360 degrees per level of insertion of the aforementioned penetration instrument in the bone structure.



- [0011] Preferably, the aforementioned device comprises a plurality of angularly spaced coinciding fixed electrodes and that the means to measure the impedance delivers a signal corresponding to each of the aforementioned electrodes.
- [0012] Advantageously, the aforementioned electrodes consist of punctual contacts longitudinally and angularly spaced out.
- [0013] Advantageously, the aforementioned electrodes are formed by longitudinal strips.
- [0014] According to one specific configuration of the invention, the electrodes are distributed around the longitudinal axis of the penetration instrument.
- [0015] Advantageously, the electrodes are symmetrically arranged with respect to the longitudinal axis of the aforementioned penetration instrument.
- [0016] Advantageously, the aforementioned electrodes consist of conducting rods of circular, semi-annular, rectangular and/or triangular section. In addition, they may consist of eccentric conducting rods.
- [0017] According to the realm of intervention in which the penetration instrument is used, the aforementioned device may comprise at least one electrode at its distal end(s). Advantageously, the aforementioned device comprises two electrodes arranged at the distal end of the aforementioned penetration instrument, the aforementioned electrodes consisting of conducting rods of concentric circular section.
- [0018] Advantageously, the aforementioned means of detection consists of visual marking preferably on the handle of the aforementioned exploration device. According to one specific means of creation of the device, the aforementioned handle (6) forms the aforementioned means of detection.

[0019] Advantageously, the aforementioned device also comprises a central channel for the passage of an additional instrument.

[0020] Now, the invention will better be understood using the following description that is only provided for explanatory purposes, with reference to the appended figures:

- figure 1 illustrates a diagram of an exploration device according to the invention;
- figure 2 illustrates a front cutaway view of the distal end of the penetration instrument according to a first configuration of the invention;
- figure 3 illustrates a longitudinal cutaway view of the penetration instrument according to a second configuration of the invention;
- figure 4 illustrates a front cutaway view of the distal end of the penetration instrument according to a third configuration of the invention;
- figure 5 illustrates a perspective view of the penetration instrument according to a fourth configuration of the invention; and
- figure 6 illustrates a longitudinal cutaway view of the penetration instrument according to a fifth configuration of the invention.

[0021] According to the invention, the exploration device (1), illustrated in figure 1, is a device enabling the monitoring of the penetration of an instrument (2) in the bone structures of a human or animal body, the aforementioned structures presenting at least two different zones of electrical impedance.

[0022] The exploration device (1) comprises a source of voltage (not represented) supplying at least two electrodes and a means to measure the impedance (not represented) between the aforementioned electrodes.

[0023] At least one of the aforementioned electrodes is found on the aforementioned penetration instrument (2).

[0024] The aforementioned device also comprises means of signalling producing a signal at the time of detection, by impedometer, a variation of impedance, and therefore the presence of a gap. The aforementioned means of signalling consist of the emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator, etc.).

[0025] According to one advantageous mode of creation of the invention, the aforementioned device also comprises means for the acquisition and visualisation of the position of the gaps during the penetration of the instrument (2) in the bone structure.

[0026] According to the applications considered, the penetration instrument (2) may either be fixed, or manually driven in rotation by means of drive of the motor type (not represented).

[0027] Therefore, it may consist, in the first configuration, for example of a probe, a square tip, a spatula, a curette or other, and in the second configuration, for example of a screw, a drill, a tap, or other.

[0028] In the following section, the penetration instrument (2) consists of a probe (2). However, the configurations presented are of course applicable to the other penetration instruments mentioned above.

[0029] Figure 2 illustrates the first configuration of the probe (2) forming the aforementioned exploration device (1).

[0030] In this first configuration, the penetration instrument (2) presents two eccentric electrodes (3, 4) of circular section at its distal end, electrode (3) being surrounded but separated from electrode (4) by an insulation ring (5).

[0031] In this example, electrode (3) comprises the positive pole of the aforementioned electronic device, the negative pole of the aforementioned electronic device consisting of the electrode (4). It is obvious that this is only one example of a creation and that the man of the art may create an electronic device whose positive pole consists of the electrode (4) and the negative pole of the electrode (3) without going beyond the invention.

[0032] Each electrode (3, 4) is arranged so as to coincide with the surface of the aforementioned penetration instrument (2).

[0033] To avoid any disturbance of the signal, the surface of the central or internal electrode (3) coinciding with the surface of the aforementioned penetration instrument (2) remains relatively small with respect to the dimensions of the hole made in the bone cortex during the drilling (or other) operation.

[0034] The position of the electrode (3) is detected by specific marking on the aforementioned exploration device (1). Advantageously, the marking is carried out by means of the handle (6) of the aforementioned exploration device (1). It may, for example, consist of a visual signal, for example an arrow, represented on the handle (6). The marking may also consist of any means directly on the handle (6), such as, for example, a specific shape of the aforementioned handle (6).

[0035] Therefore, during the penetration of the instrument (2) in the perforated bone structure, a signal is given off by the aforementioned means of signalling when a variation in impedance measured between the electrodes (3, 4) is detected by the impedometer, indicating the presence of a gap.

- [0036] Following this detection, the means of signalling emit a warning signal (visual, sound or tactile). The practitioner then knows that the electrode (3) from the penetration instrument is positioned in front of a gap.
- [0037] The practitioner then determines the direction of the gap with the mark corresponding to the position of the electrode (3) marked on the handle (6) of the aforementioned exploration device (1).
- [0038] In order to enable full scanning of the bone structure, the aforementioned penetration instrument (2) is endowed with a movement of rotation, the speed of rotation exceeding the speed of progress of the penetration instrument (2) in the bone structure. In other terms, the speed of rotation of the aforementioned instrument (2) is such that the aforementioned penetration instrument (2) sweeps at least 360 degrees by level of penetration.
- [0039] Figure 3 illustrates a second configuration of the probe (2) comprising the aforementioned exploration device (1), which enables the detection of gaps laterally arranged with respect to the body of the aforementioned penetration instrument (2).
- [0040] In this second configuration, the electrode (3) is positioned in the aforementioned penetration instrument (2) so as to punctually coincide with the lateral surface of the aforementioned penetration instrument (2).
- [0041] As for the electrode (4), it is distributed on the rest of the lateral surface of the aforementioned penetration instrument (2), including its distal end. The aforementioned electrodes (3, 4) are separated from each other by an insulant (5).
- [0042] The principle of detection and the determination of the direction of the gap are identical to that described above.

[0043] Figure 4 illustrates a third configuration of the probe (2) comprising the aforementioned exploration device (1), which enables detection of gaps arranged at the end of the aforementioned penetration instrument (2).

[0044] In this third configuration, the penetration instrument (2) presents three electrodes (7, 8, 9) of sensibly identical triangular section at the distal end. The aforementioned electrodes (7, 8, 9) distributed around the longitudinal axis of the penetration instrument (2) are angularly spaced. Advantageously, the angular space is identical.

[0045] Since the position of the electrodes (7, 8, 9) is known by the construction, their arrangement on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes for which a signal is emitted.

[0046] Since the number and triangular shape of the electrodes is given here by way of example, it is understood that the aforementioned penetration instrument (2) may present a greater number of electrodes and a shape other than triangular. The determination of the direction of the gaps is all the more exact when the number of electrodes distributed at the end of the aforementioned instrument (2) is higher.

[0047] Figure 5 illustrates another configuration of the probe (2), enabling detection of the gaps arranged at the end of the aforementioned penetration instrument (2), but also laterally.

[0048] In this configuration, the aforementioned penetration instrument (2) consists of a plurality of electrodes coinciding with the lateral surface of the aforementioned penetration instrument (2) and at the distal end of the aforementioned penetration instrument (2).

[0049] Since the position of each electrode is known, it is then possible, as in the third configuration, to determine the position of the gap by the emission of a signal by the impedometer corresponding to the electrode positioned in front of the gap.



[0050] In the configurations presented above, the means to determine the position of the gaps consist of fixed electrodes. According to a specific configuration of the aforementioned penetration instrument (2) (not represented), the gaps may also be determined by means of one or several mobile electrodes.

[0051] In addition, in the previous examples, the electrodes (3, 4) are respectively carried by the aforementioned penetration instrument (2). Of course, the aforementioned penetration instrument (2) may be equipped with only one electrode (3), the other electrode being positioned on the patient, and more specifically, on a surface other than the surgical wound, without going beyond the field of the invention.

[0052] As specified above, the configurations presented remain applicable to the other penetration instruments mentioned above.

[0053] In particular, in the case where the penetration instrument (2) consists of a drill element, the aforementioned penetration instrument (2) may advantageously comprise at least one electrode (13) coinciding with the lateral surface of the aforementioned penetration instrument (2), as well as two electrodes (10, 11) concentrically arranged at the distal end of the aforementioned penetration instrument (2) (figure 6). It is therefore possible, due to the configuration of the aforementioned penetration instrument (2) to determine the presence and direction of a gap by means of electrodes (11 and 13), as well as prevent any possible perforation of the bone cortex using electrodes (10 and 11). For this purpose, the positioning of a lateral electrode consisting of a rod extending to the distal end should be avoided. In fact, it would be impossible, with such a configuration, to know whether the zone detected by the electrodes is lateral or distal.

[0054] The invention is described above by way of example. It is understood that the man of the art is able to create different variants of the invention without going outside of the patent.

CLAIMS

1. Exploration device (1) to monitor the penetration of an instrument (2) in an anatomic structure, in particular a bone structure, comprising a source of voltage supplying at least two electrodes (3, 4) and a means to measure the impedance between the aforementioned electrodes (3, 4), characterised in that the aforementioned device (1) comprises a means of angular location formed by at least one electrode (3) punctually coinciding with a peripheral surface of the aforementioned penetration instrument (2), the coinciding surface of the aforementioned electrode (3) having a position set off from the longitudinal axis of the aforementioned instrument, as well as a means of detection of the position of the at least one aforementioned electrode (3).
2. Exploration device (1) according to claim 1, characterised in that the aforementioned electrode (3) punctually coincides with the lateral surface of the aforementioned penetration instrument (2).
3. Exploration device (1) according to claim 1 or claim 2, characterised in that the aforementioned electrode (3) punctually coincides with the peripheral surface of the distal end of the aforementioned penetration instrument (2).
4. Exploration device (1) according to any of the previous claims, characterised in that the aforementioned coinciding electrode (3) is moved in rotation.

5. Exploration device (1) according to the previous claim, characterised in that the aforementioned coinciding electrode (3) is driven at a speed of rotation so that the aforementioned electrode (3) sweeps at least 360 degrees per level of drilling of the aforementioned penetration instrument (2) in the bone structure.
6. Exploration device (1) according to claim 1, characterised in that comprises a plurality of coinciding angularly spaced fixed electrodes (3, 4, 7, 8, 9) and that the means of measurement of the impedance delivers a signal corresponding to each of the aforementioned electrodes (3, 4, 7, 8, 9).
7. Exploration device (1) according to claim 6, characterised in that the aforementioned electrodes (3, 4, 7, 8, 9) consist of longitudinally and angularly spaced punctual contacts.
8. Exploration device (1) according to claim 6, characterised in that the aforementioned electrodes (3, 4, 7, 8, 9) are formed of longitudinal strips.
9. Exploration device (1) according to any of claims 6 to 8, characterised in that the electrodes (3, 4, 7, 8, 9) are distributed around the longitudinal axis of the penetration instrument (2).

10. Exploration device (1) according to any of claims 6 to 9, characterised in that the electrodes (3, 4, 7, 8, 9) are symmetrically arranged with respect to the longitudinal axis of the aforementioned penetration instrument (2).
11. Exploration device (1) according to any of claims 6 to 10, characterised in that the aforementioned electrodes (3, 4, 7, 8, 9) consist of conducting rods of circular, semi-annular, rectangular and/or triangular section.
12. Exploration device (1) according to any of claims 6 to 11, characterised in that the aforementioned electrodes are formed by eccentric conducting rods.
13. Exploration device (1) according to any of the previous claims, characterised in that the aforementioned device (1) also comprises at least one electrode arranged at the distal end of the aforementioned penetration instrument.
14. Exploration device (1) according to the previous claim, characterised in that the aforementioned device (1) comprises two electrodes arranged at the distal end of the aforementioned penetration instrument, the aforementioned electrodes consisting of conducting rods of concentric circular section.
15. Exploration device (1) according to any of the previous claims, characterised in that the aforementioned means of detection consists of a visual marking preferably on the handle (6) of the aforementioned exploration device (1).

16. Exploration device (1) according to any of the previous claims, characterised in that the exploration device (1) comprises a handle (6) forming the aforementioned means of detection.

17. Exploration device (1) according to any of the previous claims, characterised in that it comprises a handle forming the aforementioned means of detection.

18. Exploration device (1) according to any of the previous claims, characterised in that it comprises a central channel for the passage of an additional instrument.



EXPLORATION DEVICE TO MONITOR THE...  
Inventors: Maurice Bourdon et al.  
BMC: EV 546524558 US  
Sheet 1 of 4  
Docket No.: BDM-06-1208  
DLA Piper Rudnick Gray Cary US LLP: (215) 656-3381

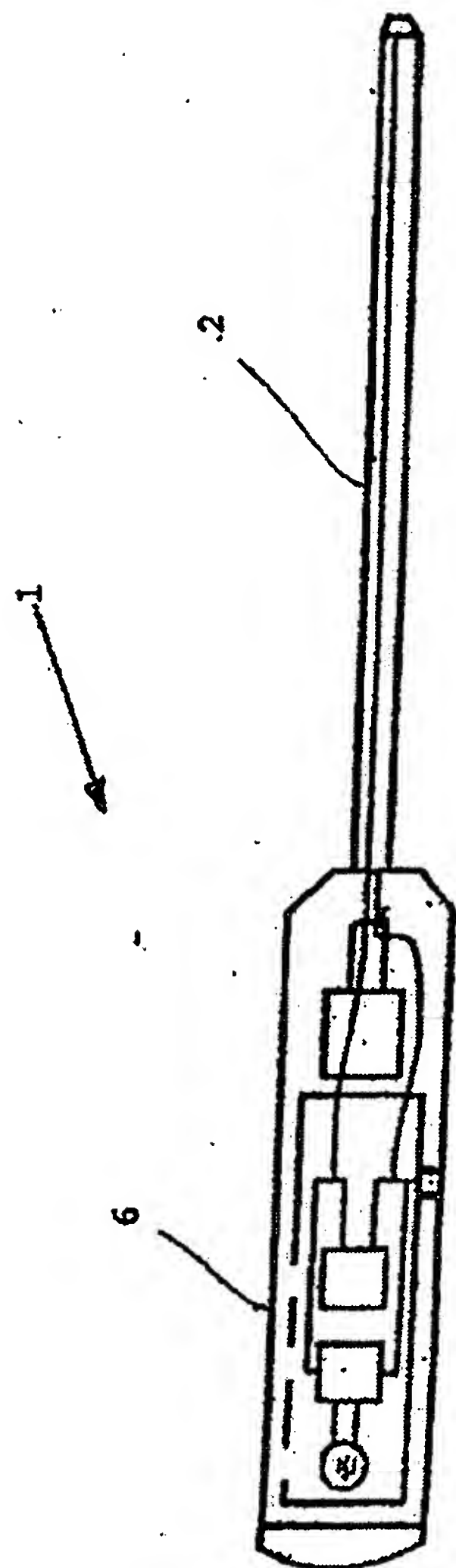


Fig. 1

EXPLORATION DEVICE TO MONITOR THE...  
Inventors: Maurice Boulton et al.  
SMC: EV 548524558 US  
Sheet 2 of 4  
Docket No.: BDM-06-1208  
DLA Piper Rudnick Gray Cary US LLP: (215) 656-3381

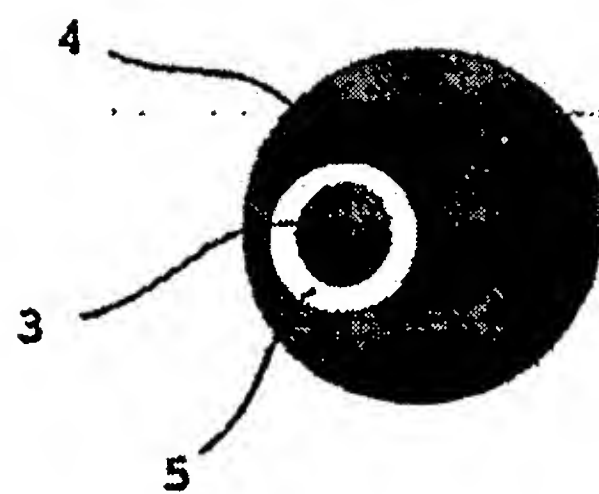


Fig. 2

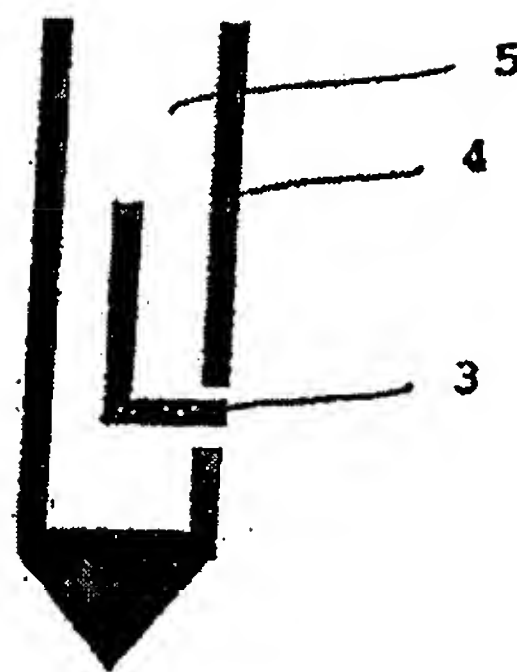


Fig. 3

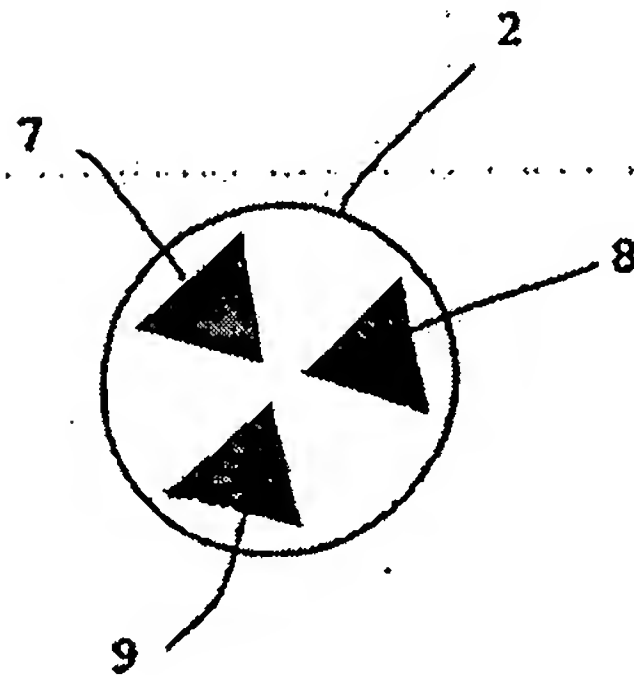


Fig. 4

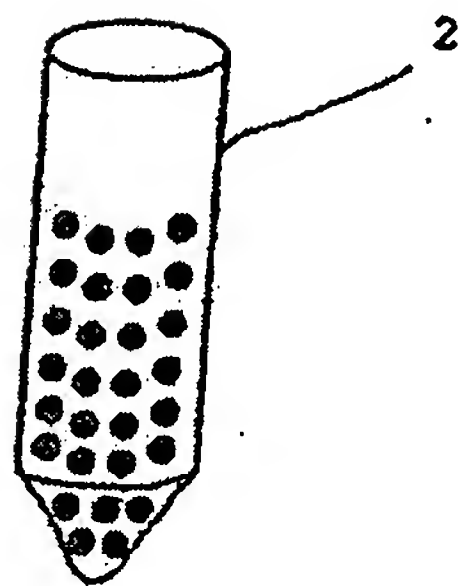


Fig. 5

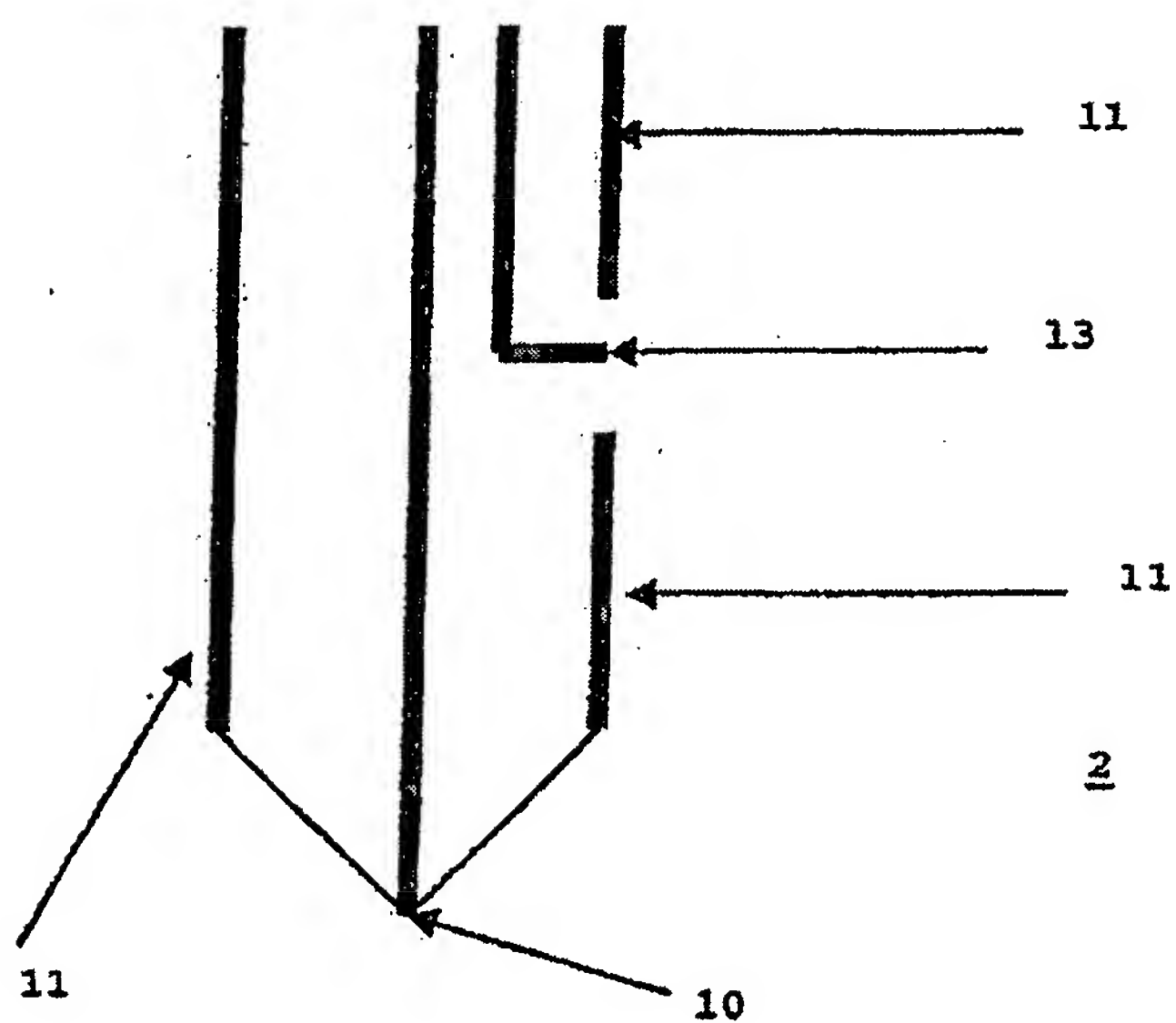


Fig. 6

SUBSTITUTE SPECIFICATION (Clean Copy)

EXPLORATION DEVICE TO MONITOR THE PENETRATION  
OF AN INSTRUMENT IN AN ANATOMIC STRUCTURE

Related Application

[0001] This is a §371 of International Application No. PCT/FR2005/000338, with an international filing date of February 11, 2005 (WO 2005/077282 A1, published August 25, 2005), which is based on French Patent Application No. 04/01361, filed February 11, 2004.

Technical Field

[0002] This invention refers to the field of spinal surgery.

Background

[0003] In surgery of the spine, for example, for pedicular drilling, the bone cortex is often crossed, broken or damaged by the drilling instrument, that may then lead to poor positioning of the pedicular screws. Following this poor positioning, the pedicular screws, inducing pain, paralysis, haemorrhage, etc. in the patient, may require another surgical intervention or, in certain cases, cause irreparable damage.

[0004] FR 2 835 732 discloses a device to monitor penetration of an instrument (drill or other type of instrument) in the vertebra by measuring the differences in the electrical impedance during penetration so that the practitioner is constantly aware whether the end of the instrument is leaving the bone cortex and penetrating into a zone of soft tissue (marrow, nerves, tissue). In that case, the practitioner modifies the path of the penetration instrument to return to the bone cortex.

[0005] Such a device may also be used to detect the formation of a gap in the bone cortex during drilling.

[0006] To facilitate repositioning of the penetration instrument during a drilling operation (or similar type of operation such as tapping, boring, etc.), but also to enable proper positioning of the pedicular screw or any other surgical instrument, the practitioner has to know the exact position of the gaps formed during the drilling.

[0007] It could therefore be advantageous to provide an exploration device indicating the position of the gaps formed during a drilling (or similar) operation.

#### Summary

[0008] This invention relates to an exploration device to monitor the penetration of an instrument in an anatomic structure including at least two electrodes, a source of voltage supplying the at least two electrodes, a means for measuring impedance between the electrodes, a means of angular location formed by at least one electrode punctually coinciding with a peripheral surface of the penetration instrument, the coinciding surface of the electrode having a position set off from a longitudinal axis of the instrument, and means for detecting a position of the at least one electrode.

#### Brief Description of the Drawings

[0009] Selected, representative aspects will be better understood using the following description that is only provided for explanatory purposes, with reference to the appended figures:

Fig. 1 is a diagram of an exploration device;



Fig. 2 is a front cutaway view of the distal end of the penetration instrument according to one configuration;

Fig. 3 is a longitudinal cutaway view of the penetration instrument according to another configuration;

Fig. 4 is a front cutaway view of the distal end of the penetration instrument according to still another configuration;

Fig. 5 is a perspective view of the penetration instrument according to yet another configuration; and

Fig. 6 is a longitudinal cutaway view of the penetration instrument according to a further configuration.

#### Detailed Description

[0010] We disclose exploration devices to monitor penetration of an instrument in an anatomic structure, in particular bone structure, comprising a source of voltage supplying at least two electrodes and a means to measure the impedance between the electrodes. The device includes a means of angular location formed by at least one electrode punctually coinciding with a peripheral surface of the penetration instrument, the coinciding surface of the electrode whose position is set off from the longitudinal axis of the instrument, as well as a means to detect the position of the electrode.

[0011] By "punctual coincidence" and "punctually coinciding," we mean a contact surface partially and discontinually coinciding with the peripheral surface of the aforementioned penetration instrument. In particular, an angular contact surface, and by extension a tubular shape are not considered as providing punctual coincidence.

- [0012] Depending on whether one desires taking lateral readings or readings at the end of the penetration instrument or laterally and at the end, respectively, the penetration instrument may be equipped with at least one electrode coinciding with the lateral surface of the penetration instrument and/or at least one electrode coinciding with the peripheral surface of the distal end of the penetration instrument.
- [0013] Advantageously, the coinciding electrode is driven in rotation, the coinciding electrode being driven at speed of rotation so that it sweeps at least 360 degrees per level of insertion of the penetration instrument in the bone structure.
- [0014] The device may comprise a plurality of angularly spaced coinciding fixed electrodes and the means to measure the impedance delivers a signal corresponding to each of the electrodes.
- [0015] The electrodes may consist of punctual contacts longitudinally and angularly spaced out.
- [0016] The electrodes may be formed by longitudinal strips.
- [0017] According to one selected configuration, the electrodes are distributed around the longitudinal axis of the penetration instrument.
- [0018] The electrodes may be symmetrically arranged with respect to the longitudinal axis of the penetration instrument.
- [0019] The electrodes may consist of conducting rods of circular, semi-annular, rectangular and/or triangular section. In addition, they may consist of eccentric conducting rods.
- [0020] According to the realm of intervention in which the penetration instrument is used, the device may comprise at least one electrode at its distal end(s). The device may also comprise

two electrodes arranged at the distal end of the penetration instrument, the electrodes consisting of conducting rods of concentric circular section.

[0021] The means of detection may consist of visual marking preferably on the handle of the exploration device. According to one specific means of creation of the device, the handle forms the means of detection.

[0022] The device may also comprise a central channel for the passage of an additional instrument.

[0023] Turning now to the Drawings, the exploration device (1), illustrated in Fig. 1, is a device enabling the monitoring of the penetration of an instrument (2) in the bone structures of a human or animal body, the structures having at least two different zones of electrical impedance.

[0024] The exploration device (1) comprises a source of voltage (not shown) supplying at least two electrodes and a means to measure the impedance between the electrodes.

[0025] At least one of the electrodes is found on the penetration instrument (2).

[0026] The device also comprises means for signalling producing a signal at the time of detection, by impedometer, a variation of impedance, and therefore the presence of a gap. The means for signalling includes emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator, etc.).

[0027] The device may also comprise means for the acquisition and visualisation of the position of the gaps during penetration of the instrument (2) in the bone structure.

[0028] According to the applications considered, the penetration instrument (2) may either be fixed, or manually driven in rotation by means of drive of the motor type (not shown).

[0029] Therefore, it may include in one configuration, for example, of a probe, a square tip, a spatula, a curette or other, and in a second configuration, for example, of a screw, a drill, a tap, or other.

[0030] In the following section, the penetration instrument (2) includes a probe (2). However, the configurations presented are of course applicable to other penetration instruments mentioned above.

[0031] Fig. 2 illustrates one configuration of the probe (2) forming the exploration device (1).

[0032] In this configuration, the penetration instrument (2) has two eccentric electrodes (3, 4) of circular section at its distal end, electrode (3) being surrounded but separated from electrode (4) by an insulation ring (5).

[0033] In this example, electrode (3) comprises the positive pole of the electronic device, the negative pole of the electronic device comprising the electrode (4). This is only one example of an electronic device whose positive pole includes the electrode (4) and the negative pole of the electrode (3). Variations are within the skill in the art.

[0034] Each electrode (3, 4) is arranged to coincide with the surface of the penetration instrument (2).

[0035] To avoid any disturbance of the signal, the surface of the central or internal electrode (3) coinciding with the surface of the penetration instrument (2) remains relatively small with respect to the dimensions of the hole made in the bone cortex during the drilling (or other) operation.

[0036] The position of the electrode (3) is detected by specific marking on the exploration device (1). Advantageously, the marking is carried out by means of the handle (6) of the

exploration device (1). It may, for example, include a visual signal, for example, an arrow, represented on the handle (6). The marking may also include any means directly on the handle (6), such as, for example, a specific shape of the handle (6).

[0037] Therefore, during penetration of the instrument (2) in the perforated bone structure, a signal is given off by the means for signalling when a variation in impedance measured between the electrodes (3, 4) is detected by the impedometer, indicating the presence of a gap.

[0038] Following such detection, the means for signalling emit a warning signal (visual, sound or tactile). The practitioner then knows that the electrode (3) from the penetration instrument is positioned in front of a gap.

[0039] The practitioner then determines the direction of the gap with the mark corresponding to the position of the electrode (3) marked on the handle (6) of the exploration device (1).

[0040] In order to enable full scanning of the bone structure, the penetration instrument (2) is endowed with a movement of rotation, the speed of rotation exceeding the speed of progress of the penetration instrument (2) in the bone structure. In other words, the speed of rotation of the instrument (2) is such that the aforementioned penetration instrument (2) sweeps at least 360 degrees by level of penetration.

[0041] Fig. 3 illustrates another configuration of the probe (2) comprising the exploration device (1), which enables detection of gaps laterally arranged with respect to the body of the penetration instrument (2).

[0042] In this configuration, the electrode (3) is positioned in the penetration instrument (2) to punctually coincide with the lateral surface of the penetration instrument (2).

[0043] As for the electrode (4), it is distributed on the rest of the lateral surface of the penetration instrument (2), including its distal end. The electrodes (3, 4) are separated from each other by an insulant (5).

[0044] The principle of detection and the determination of the direction of the gap are identical to that described above.

[0045] Fig. 4 illustrates another configuration of the probe (2) comprising the exploration device (1), which enables detection of gaps arranged at the end of the penetration instrument (2).

[0046] In this configuration, the penetration instrument (2) has three electrodes (7, 8, 9) of sensibly identical triangular section at the distal end. The electrodes (7, 8, 9) distributed around the longitudinal axis of the penetration instrument (2) are angularly spaced. Advantageously, the angular space is identical.

[0047] Since the position of the electrodes (7, 8, 9) is known by the construction, their arrangement on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes for which a signal is emitted.

[0048] Since the number and triangular shape of the electrodes is given here by way of example, it is understood that the penetration instrument (2) may have a greater number of electrodes and a shape other than triangular. The determination of the direction of the gaps is all the more exact when the number of electrodes distributed at the end of the instrument (2) is higher.

[0049] Fig. 5 illustrates another configuration of the probe (2), enabling detection of the gaps arranged at the end of the penetration instrument (2), but also laterally.



[0050] In this configuration, the penetration instrument (2) includes a plurality of electrodes coinciding with the lateral surface of the penetration instrument (2) and at the distal end of the penetration instrument (2).

[0051] Since the position of each electrode is known, it is then possible to determine the position of the gap by the emission of a signal by the impedometer corresponding to the electrode positioned in front of the gap.

[0052] In the configurations presented above, the means to determine the position of the gaps include fixed electrodes. According to yet another configuration of the penetration instrument (2) (not shown), the gaps may also be determined by means of one or several mobile electrodes.

[0053] In addition, in the previous examples, the electrodes (3, 4) are respectively carried by the penetration instrument (2). Of course, the penetration instrument (2) may be equipped with only one electrode (3), the other electrode being positioned on the patient, and more specifically, on a surface other than the surgical wound, without going beyond the field of the invention.

[0054] As specified above, the configurations presented remain applicable to the other penetration instruments mentioned above.

[0055] In particular, in the case where the penetration instrument (2) includes a drill element, the penetration instrument (2) may advantageously comprise at least one electrode (13) coinciding with the lateral surface of the penetration instrument (2), as well as two electrodes (10, 11) concentrically arranged at the distal end of the penetration instrument (2) (Fig. 6). It is therefore possible, due to the configuration of the penetration instrument (2) to determine the presence and direction of a gap by means of electrodes (11 and 13), as well as prevent any possible perforation of the bone cortex using electrodes (10 and 11). For this purpose, the positioning of a lateral electrode consisting of a rod extending to the distal end should be

avoided. If fact, it would likely be impossible with such a configuration to know whether the zone detected by the electrodes is lateral or distal.

[0056] This disclosure is described above by way of example. It is understood that one skilled in the art is able to create different variations of the structures described and/or shown without departing from the subject matter recited in the appended claims.

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Toque No : J033

September, 19, 2007-10-03

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O/Ref. : PASRV/757056.1  
Case ref. : W1210/00158

Mister Gérard Vanacker  
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2 rue du Sautiquet  
83380 Les Issambres

**Registered letter with  
acknowledgement of receipt**

**FILING OF INTERNATIONAL APPLICATION  
PCT/FR2005/00338 IN THE USA**

Dear Sir,

We are the legal advisers of company SpineVision SA.

In view of the registration of the US application No. 10/589,182 filed on August, 11, 2006 (35904/PCT/US) and corresponding to international application PCT/FR2005/00338 (Title : « Exploration device to monitor the penetration of an instrument in an anatomic structure »), relating to an invention for which you are one of the designated inventors, our client has asked us to transmit the following documents to you :

- a corrected copy of « Combined Declaration, Power of Attorney and Petition »,
- a corrected copy of « Assignment »,
- a copy of the publication pamphlet of the application application PCT/FR2005/00338,
- a copy of the application text as filed in the USA
- a copy of the US substitute text.

Kindly review these documents and send back to us the document « Combined Declaration, Power of Attorney and Petition » and the document « Assignment », both of them duly executed by yourself.

Mister Gérard Vanacker

- 2 -

September, 19, 2007

Indeed these documents are absolutely needed by our client in order to obtain the grant of the American patent corresponding to said international application.

We thank you in advance for your kind and prompt co-operation and inform you that, according to our ethical rules, we forward a copy of the present letter to your legal counsel, our colleague Guillaume Teissonnière.

Yours sincerely,

*Signed*

Dominique Ménard  
Attorney at Law

Destinataire  
 1. Gerard VANACKER  
 VILLA SAINT ANTOINE  
 9 rue du Santiquet  
 93380 LES ISSAMBLES

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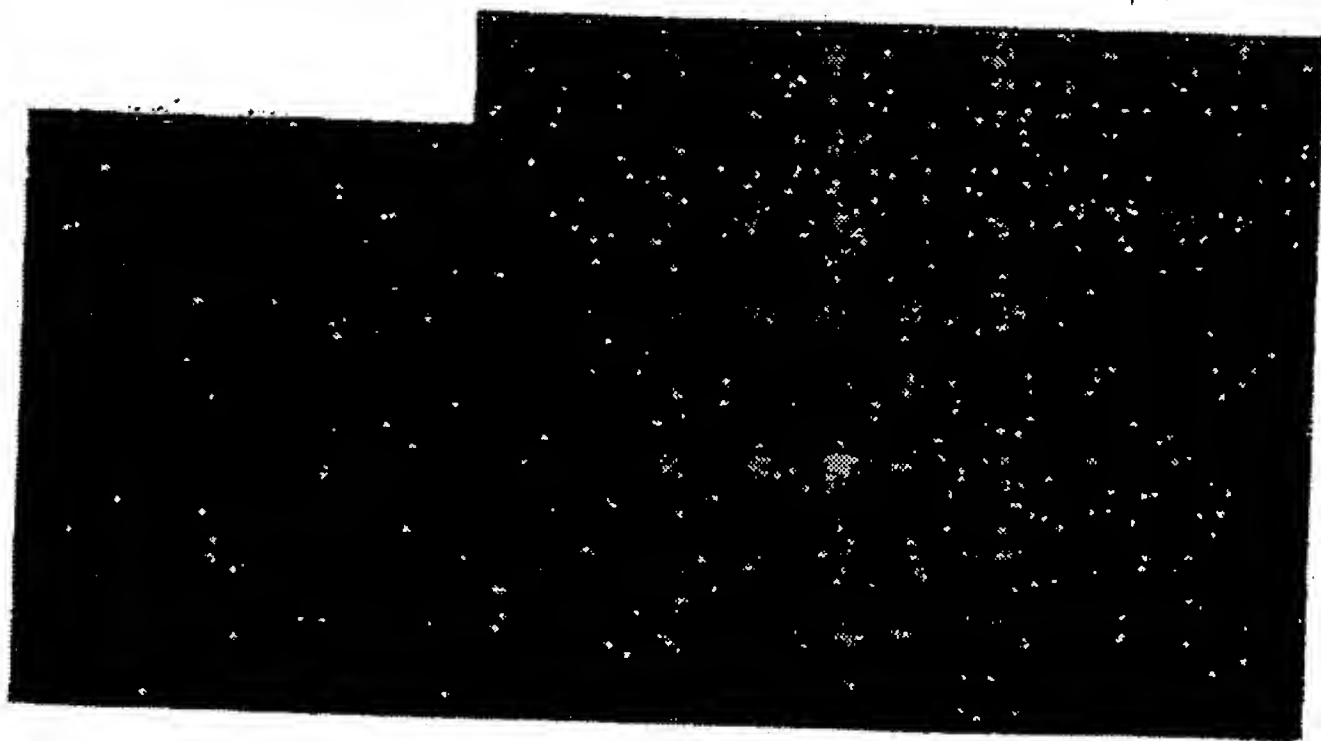
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